

US EPA ARCHIVE DOCUMENT



**Terms and Conditions for
Bt Corn Registrations**

September 30, 2010

**Office of Pesticide Programs
U.S. Environmental Protection Agency**

**Terms and Conditions for
Bt Corn Registrations
30 September 2010
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I. Cry 1Ab and Cry 1F BRAD Registered Products

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Syngenta	67979-1	<i>Bt</i> corn Event <i>Bt</i> 11 with Cry1Ab (AgriSure CB/LL; field corn)	August 1996	Unconditional, Time-Limited (converted 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to *Bacillus thuringiensis* corn Event *Bt* 11 with Cry 1Ab for use in field corn.
- 3] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 4] You must do the following Insect Resistance Management Program:

Insect Resistance Management:

The required IRM program for *Bt* corn must have the following elements:

- 1] Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;
- 2] Requirements for Syngenta Seeds, Inc. (Syngenta) to prepare and require *Bt* corn users to sign “grower agreements” that impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements regarding programs to educate growers about IRM requirements;
- 4] Requirements regarding programs to evaluate and promote growers’ compliance with IRM requirements;
- 5] Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1Ab protein in the target insects;
- 6] Requirements regarding a “remedial action plan” that contains measures Syngenta would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- 7] Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the education program on or before January 31st each year.

a. Refuge Requirements

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

1] Corn-Belt Refuge Requirements

Field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB) and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2] Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 50% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the

edges or headlands), and strips across the field.

- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated-protectants, which is reasonably likely to assure that persons purchasing Bt11 Insect Protected Field Corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] Syngenta must continue to use its current grower agreement for Bt11 Insect Protected Field Corn. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5] Syngenta must continue to integrate this amended registration into the current system used for its other Bt corn plant-incorporated-protectants, which is reasonably likely to assure that persons purchasing Bt11 Insect Protected Field Corn sign grower agreement(s).

6] Syngenta shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31 of the year in which the agreement was signed.

7] Syngenta shall provide EPA with a report showing the number of units of its *Bt* corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

8] Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

1] Syngenta must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Bt11 Insect Protected Field Corn users the importance of complying with the IRM program. The program shall include information encouraging Bt11 Insect Protected Field Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 Insect Protected Field Corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt11 Insect Protected Field Corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, each January 31st, Syngenta must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Syngenta must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4] Syngenta must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11 Insect Protected Field Corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta corn PIP products. Syngenta shall coordinate with other *Bt* corn

registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.

5] Syngenta must establish and publicize a “phased compliance approach,” i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Syngenta must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to Syngenta corn PIP products the next year. Additionally, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Bt11 Insect Protected Field Corn.

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn borer protected products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

- i. A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Syngenta shall provide a written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year. Syngenta shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, Syngenta shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes.

11] Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with growers of their *Bt* corn borer protected products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] Syngenta shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Syngenta may elect to coordinate information with other registrants and report collectively the results of their compliance assurance programs.

15] Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

16] Syngenta shall revise and expand its existing Compliance Assurance Program to include the following elements. Syngenta must prepare and submit on or before January 31, 2011, a written description of its revised Compliance Assurance Program. Syngenta may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

17] Syngenta will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
- ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next

three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19] Syngenta will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from Syngenta, licensee, or affiliated company.

20] Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment

21] Syngenta will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

22] Syngenta will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within 3 years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 Insect Protected Field Corn within a 5-year period will be denied access to Syngenta corn PIP products in the subsequent year.

d. Insect Resistance Monitoring and Remedial Action Plan

The Agency is imposing the following conditions for the Cry1Ab toxin expressed in this product:

Syngenta will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

Syngenta shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; S WCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and

results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
 - determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
 - estimating the resistance-allele frequency in the original population;
 - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Syngenta will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Syngenta will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Syngenta:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

e. Annual Reports

1] Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

2] Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;

3] Grower Education: substantive changes to education program completed the previous year, January 31st each year;

4] Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;

5] Compliance: to include annual survey results and plans for the next year; full report January 31st each year;

6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Syngenta	65268-1	<i>Bt</i> corn Event <i>Bt</i> 11 with Cry1Ab (Attribute; sweet corn, no refuge)	February 1998	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to *Bacillus thuringiensis* corn Event *Bt* 11 with Cry 1Ab for use in sweet corn.
- 3] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5] The Agency is requiring protein expression data in terms of dry weight, as the amount of protein present in the given tissue, specifically for *Bt* 11 sweet corn. Tissues for which expression data must be provided include: leaf, root, pollen, seed, and whole plant. In addition, data for each of these tissues should be provided for young plants in rapid growth, during flowering, and mature plants before harvest when that part of the plant is present. Data are due on or before January 31, 2012.
- 6] You must commit to do the following Insect Resistance Management Program:

Insect Resistance Management:

The required IRM program for *Bt* corn must have the following elements:

- 1] Requirements (except for home garden use or educational use, i.e., marketed to home gardeners or educators for use on less than 20 acres) for Syngenta to prepare and require *Bt* corn users to sign “grower agreements” that impose binding contractual obligations on the grower to comply with the refuge requirements;
- 2] Requirements regarding programs to educate growers about IRM requirements;
- 3] Requirements regarding programs to evaluate and promote growers’ compliance with IRM requirements (except for home garden use or educational use, i.e., marketed to home gardeners or educators for use on less than 20 acres);
- 4] Requirements regarding programs to evaluate whether there are statistically significant and

biologically relevant changes in target insect susceptibility to Cry1Ab protein in the target insects;

5] Requirements regarding a “remedial action plan” that contains measures Syngenta would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;

6] Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the education program on or before January 31st each year.

7] For home garden or educational use, submit annual reports on total number of estimated acres sold and the compliance assurance program including the education program on or before January 31st each year.

a. Sweet Corn Post-Harvest Requirements

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide, and in the case of home gardeners on the seed packet, in seed catalogues, and on websites offering Attribute® Insect Protected Sweet Corn Hybrids for sale to home gardeners.

1. Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.

2. The allowed crop destruction methods are: rotary mowing, discing, or plow- down or (for the home garden use) by chopping up the stalks using home garden tools such as a hoe. The crop destruction methods are intended to protect against development of insect resistance

b. Grower Agreements (except for home garden use or educational use, i.e., marketed to home gardeners or educators for use on less than 20 acres)

1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.

2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Attribute® Insect Protected Sweet Corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4] Syngenta must continue to use its current grower agreement for Attribute® Insect Protected Sweet Corn. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5] Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Attribute® Insect Protected Sweet Corn sign grower agreement(s).

6] Syngenta shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31 of the year in which the agreement was signed.

7] Syngenta shall provide EPA with a report showing the number of units of its *Bt* corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

8] Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

1] Syngenta must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Attribute® Insect Protected Sweet Corn users the importance of complying with the IRM program. The program shall include information encouraging Attribute® Insect Protected Sweet Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Attribute® Insect Protected Sweet Corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Attribute® Insect Protected Sweet Corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, each January 31st, Syngenta must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report.

Syngenta must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4] Syngenta must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Attribute® Insect Protected Sweet Corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta corn PIP products (with the exception of home gardening or educational uses). Syngenta shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and continue to integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.

The following IRM Education and IRM Compliance Monitoring Programs apply to all growers who plant more than 20 acres of Bt corn:

5] Syngenta must establish and publicize a “phased compliance approach,” i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Syngenta must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to Syngenta corn PIP products the next year. Additionally, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Attribute® Insect Protected Sweet Corn.

6] The IRM compliance assurance program shall include an annual survey of all *Bt* sweet corn customers who purchase 5 or more bags of *Bt*11 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of *Bt* sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.

i. A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Syngenta shall provide a written summary of the results of the prior year’s survey (together with a description of the methodology used, and the supporting data) to EPA by January 31 of each year. Syngenta shall confer with EPA on changes to the design and content of the survey prior to its implementation.

10] Annually, Syngenta shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes.

11] Syngenta shall train its representatives who make on-farm visits with *Bt* corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] Syngenta shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, the registrant will meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs.

15] Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

16] Syngenta shall revise and expand its existing Compliance Assurance Program to include the following elements. Syngenta must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. Syngenta may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

Requirements 17-22 of this section shall not require any action by Syngenta until a total of 20,000 acres in any county and/or a combined U.S. total of 250,000 acres per year have been planted of Attribute® Insect Protected Sweet Corn.

17] Syngenta will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
- ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19] Syngenta will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from Syngenta, licensee, or affiliated company.

20] Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment

21] Syngenta will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

22] Syngenta will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.

- ii. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within 3 years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Attribute® Insect Protected Sweet Corn within a 5-year period will be denied access to Syngenta corn PIP products in the subsequent year.

d. Insect Resistance Monitoring and Remedial Action Plan

The Agency is imposing the following conditions for the Cry1Ab toxin expressed in this product:

Syngenta will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(2) Focused Population Sampling

Syngenta will develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which Cry1Ab sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Syngenta should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which Cry 1Ab sweet corn acreage exceeds the trigger specified in this requirement (i.e. greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Syngenta shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB) and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex

adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:

- determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Syngenta will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, CEW, and FAW), Syngenta will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Syngenta will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as

expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Syngenta:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs.

Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

e. Annual Reports

- 1] Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- 2] Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3] Grower Education: substantive changes to education program completed the previous year, January 31st each year;
- 4] Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5] Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Monsanto	524-489	<i>Bt</i> corn Event MON 810 Cry1Ab	December 1996	Unconditional, Time-Limited (converted 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to *Bacillus thuringiensis* corn Event MON 810 Cry1Ab.
- 3] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 4] You must do the following Insect Resistance Management Program:

Insect Resistance Management:

The required IRM program for *Bt* corn must have the following elements:

- 1] Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;
- 2] Requirements for Monsanto Company (Monsanto) to prepare and require *Bt* corn users to sign “grower agreements” that impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements regarding programs to educate growers about IRM requirements;
- 4] Requirements regarding programs to evaluate and promote growers’ compliance with IRM requirements;
- 5] Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1Ab protein in the target insects;
- 6] Requirements regarding a “remedial action plan” that contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;

7] Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the education program on or before January 31st each year.

a. Refuge Requirements

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by Monsanto to help these growers meet the refuge requirements across their farming operations.

1] Corn-Belt Refuge Requirements

Field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB) and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2] Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 50% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated-protectants, which is reasonably likely to assure that persons purchasing MON 810 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] Monsanto must continue to use its current grower agreement for MON 810. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or

the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] Monsanto must continue to integrate this amended registration into the current system used for its other Bt corn plant-incorporated-protectants, which is reasonably likely to assure that persons purchasing MON 810 sign grower agreement(s).

6] Monsanto shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31 of the year in which the agreement was signed.

7] Monsanto shall provide EPA with a report showing the number of units of its *Bt* corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

8] Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

1] Monsanto must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to MON 810 users the importance of complying with the IRM program. The program shall include information encouraging MON 810 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 810 fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 810 user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, each January 31st, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4] Monsanto must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 810 are complying

with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Monsanto corn PIP products. Monsanto shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.

5] Monsanto must establish and publicize a “phased compliance approach,” i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to Monsanto corn PIP products the next year. Additionally, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON 810.

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn borer protected products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

i. A third party is classified as a party other than Monsanto, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other

sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes.

11] Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of their *Bt* corn borer protected products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] Monsanto shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Monsanto may elect to coordinate information with other registrants and report collectively the results of their compliance assurance programs.

15] Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

16] Monsanto shall revise and expand its existing Compliance Assurance Program to include the following elements. Monsanto must prepare and submit on or before January 31, 2011, a written description of its revised Compliance Assurance Program. Monsanto may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

17] Monsanto will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;

- ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] Monsanto will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19] Monsanto will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from Monsanto, licensee, or affiliated company.

20] Monsanto will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment

21] Monsanto will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

22] Monsanto will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Monsanto, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Monsanto will conduct follow-up checks on growers found to be significantly out of compliance within 3 years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for MON 810 within a 5-year period will be denied access to Monsanto corn PIP products in the subsequent year.

d. Insect Resistance Monitoring and Remedial Action Plan

The Agency is imposing the following conditions for the Cry1Ab toxin expressed in this product:

Monsanto will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(3) Focused Population Sampling

Monsanto shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; S WCB), and *Helicoverpa zea* (corn earworm; CE W). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

Monsanto will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and

results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
 - determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
 - estimating the resistance-allele frequency in the original population;
 - determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Monsanto will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95%

confidence interval of the LC₅₀ for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

e. Annual Reports

- 1] Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- 2] Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3] Grower Education: substantive changes to education program completed the previous year, January 31st each year;
- 4] Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5] Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Dow/Mycogen	68467-2	<i>Bt</i> corn Event TC1507 with plant optimized (PO) Cry1F (Herculex 1)	May 2001	Unconditional, Time-Limited (converted 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to *Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 in field corn.
- 3] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 4] You must do the following Insect Resistance Management Program:

Insect Resistance Management:

The IRM terms and conditions for this product are as follows.

The required IRM program for *Bt* corn must have the following elements:

- 1] Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;
- 2] Requirements for the registrants to prepare and require *Bt* corn users to sign “grower agreements” that impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements regarding programs to educate growers about IRM requirements;
- 4] Requirements regarding programs to evaluate and promote growers’ compliance with IRM requirements;
- 5] Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F protein in the target insects;
- 6] Requirements regarding a “remedial action plan” that contains measures the registrants would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;

7] Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the education program on or before January 31st each year.

a. Refuge Requirements

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by the registrant to help these growers meet the refuge requirements across their farming operations.

1] Corn-Belt Refuge Requirements

Field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB) and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2] Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 50% non-*Bt*

corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] The registrant must maintain a system that is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] The registrant must continue to use their current grower agreement. If the registrant wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

- 5] The registrant must maintain a system that is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s).
- 6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31 of the year in which the agreement was signed.
- 7] The registrant shall provide EPA with a report showing the number of units of its *Bt* corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

- 1] The registrant must maintain a comprehensive, ongoing IRM education program designed to convey to *Bt* corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. The registrant shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Grower Association and state extension programs.
- 2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3] Annually, each January 31st, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).
- 4] The registrant must maintain an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the registrant's *Bt* corn products. The registrant shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this registration into the current

compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.

5] The registrant must maintain and publicize a “phased compliance approach,” i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to the registrant’s *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn borer protected products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] The registrant shall provide a written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year. The registrant shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes.

11] The registrant shall conduct an annual on-farm assessment program. The registrant shall train its representatives who make on-farm visits with growers of their *Bt* corn borer protected

products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs.

15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

16] The registrant shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

17] The registrant will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
- ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed

bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] The registrant will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19] The registrant will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

20] The registrant will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment

21] The registrant will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

22] The registrant will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by the registrant, seed supplier, or third party assessor, after completing the assessment process;
- ii. The registrant will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access to the registrant's *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan

The Agency is imposing the following conditions for the Cry 1F toxin expressed in this product:

The registrant will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(4) Focused Population Sampling

The registrant shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:

- determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, the registrant will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target

Pests:

The registrant will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. The registrant will instruct its customers to contact them if such incidents occur. The registrant will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), the registrant will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;

- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, the registrant will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, the registrant will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by the registrant:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- The registrant will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. The registrant will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

e. Annual Reports

1] Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

- 2] Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3] Grower Education: substantive changes to education program completed the previous year, January 31st each year;
- 4] Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5] Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer/Dupont	29964-3	<i>Bt</i> corn Event TC1507 with plant optimized (PO) Cry1F (Herculex 1)	May 2001	Unconditional, Time-Limited (converted 29 September 2010)	30 September 2015

1] The subject registration will automatically expire on midnight September 30, 2015.

2] The subject registration will be limited to : *Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 in field corn.

3] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

4] You must do the following Insect Resistance Management Program:

Insect Resistance Management:

The IRM terms and conditions for this product are as follows.

The required IRM program for *Bt* corn must have the following elements:

1] Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;

2] Requirements for the registrants to prepare and require *Bt* corn users to sign “grower agreements” that impose binding contractual obligations on the grower to comply with the refuge requirements;

3] Requirements regarding programs to educate growers about IRM requirements;

4] Requirements regarding programs to evaluate and promote growers’ compliance with IRM requirements;

5] Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F protein in the target insects;

6] Requirements regarding a “remedial action plan” that contains measures the registrants would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;

7] Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the education program on or before January 31st each year.

a. Refuge Requirements

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by the registrant to help these growers meet the refuge requirements across their farming operations.

1] Corn-Belt Refuge Requirements

Field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB) and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2] Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 50% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as

needed to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] The registrant must maintain a system that is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] The registrant must continue to use their current grower agreement. If the registrant wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

- 5] The registrant must maintain a system that is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s).
- 6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31 of the year in which the agreement was signed.
- 7] The registrant shall provide EPA with a report showing the number of units of its *Bt* corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

- 1] The registrant must maintain a comprehensive, ongoing IRM education program designed to convey to *Bt* corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. The registrant shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Grower Association and state extension programs.
- 2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3] Annually, each January 31st, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).
- 4] The registrant must maintain an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the registrant's *Bt* corn products. The registrant shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.

5] The registrant must maintain and publicize a “phased compliance approach,” i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to the registrant’s *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn borer protected products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] The registrant shall provide a written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year. The registrant shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes.

11] The registrant shall conduct an annual on-farm assessment program. The registrant shall train its representatives who make on-farm visits with growers of their *Bt* corn borer protected products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower

who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs.

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- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
- ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

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- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19] The registrant will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

20] The registrant will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

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- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by the registrant, seed supplier, or third party assessor, after completing the assessment process;
- ii. The registrant will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access to the registrant's *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan

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relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

The registrant shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; S WCB), and *Helicoverpa zea* (corn earworm; CE W). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt*

corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:

- determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, the registrant will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

The registrant will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. The registrant will instruct its customers to contact them if such incidents occur. The registrant will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), the registrant will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and

that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, the registrant will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, the registrant will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by the registrant:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- The registrant will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. The registrant will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

e. Annual Reports

1] Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

2] Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;

- 3] Grower Education: substantive changes to education program completed the previous year, January 31st each year;
- 4] Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5] Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Dow Agrosciences	68467-4	<i>Bt</i> Cry1F Event DAS-06274-8 corn	27 May 2005	Unconditional, Time-Limited (converted 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to : *Bacillus thuringiensis* var. *aizawai* strain PS811 Cry1F protein and the genetic material necessary for its production (plasmid insert PHP12537) in corn event DAS-Ø6275-8 in field corn.
- 3] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 4] You must do the following Insect Resistance Management Program:

The following registration requirements and conditions shall not require any action by Mycogen Seeds c/o Dow AgroSciences LLC unless and until Mycogen Seeds c/o Dow AgroSciences LLC commercializes moCry1F corn in the United States. The term “commercialization” shall mean the sale of moCry1F corn seed to one or more growers for the purposes of growing a commercial grain corn crop in the United States.

Insect Resistance Management:

The required IRM program for *Bt* corn must have the following elements:

- 1] Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;
- 2] Requirements for the registrants to prepare and require *Bt* corn users to sign “grower agreements” that impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements regarding programs to educate growers about IRM requirements;
- 4] Requirements regarding programs to evaluate and promote growers’ compliance with IRM requirements;
- 5] Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F protein in the target insects;
- 6] Requirements regarding a “remedial action plan” that contains measures the registrants would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;

7] Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the education program on or before January 31st each year.

a. Refuge Requirements

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by the registrant to help these growers meet the refuge requirements across their farming operations.

1] Corn-Belt Refuge Requirements

Field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB) and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2] Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 50% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] The registrant must maintain a system that is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] The registrant must continue to use their current grower agreement. If the registrant wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior

to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] The registrant must maintain a system that is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s).

6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31 of the year in which the agreement was signed.

7] The registrant shall provide EPA with a report showing the number of units of its *Bt* corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

1] The registrant must maintain a comprehensive, ongoing IRM education program designed to convey to *Bt* corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. The registrant shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Grower Association and state extension programs.

2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, each January 31st, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4] The registrant must maintain an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access the registrant's *Bt* corn products. The registrant shall coordinate with other *Bt* corn registrants in improving its

compliance assurance program and continue to integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.

5] The registrant must maintain and publicize a “phased compliance approach,” i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to the registrant’s *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn borer protected products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] The registrant shall provide a written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year. The registrant shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes.

11] The registrant shall conduct an annual on-farm assessment program. The registrant shall train its representatives who make on-farm visits with growers of their *Bt* corn borer protected products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs.

15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

16] The registrant shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

17] The registrant will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
- ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP

product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] The registrant will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19] The registrant will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

20] The registrant will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment

21] The registrant will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

22] The registrant will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by the registrant, seed supplier, or third party assessor, after completing the assessment process;
- ii. The registrant will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access to the registrant's *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan

The Agency is imposing the following conditions for the Cry1F toxin Expressed in this product:

The registrant will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(2) Focused Population Sampling

The registrant shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:

- determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, the registrant will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

The registrant will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. The registrant will instruct its customers to contact them if such incidents occur. The registrant will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), the registrant will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and

- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, the registrant will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, the registrant will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by the registrant:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- The registrant will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. The registrant will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

e. Annual Reports

1] Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

- 2] Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3] Grower Education: substantive changes to education program completed the previous year, January 31st each year;
- 4] Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5] Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer/Dupont	29964-7	1507 (PO Cry1F) x MON 810 (Cry1Ab)	24 February 2010	Conditional	31 October 2010

Pioneer Hi-Bred International Corn PIP Products

Three Pioneer Hi-Bred International corn PIP products (1507 X MON810, EPA Reg No. 29964-7; 1507 X 59122 X MON810, EPA Reg. No 29964-8; and 59122 X MON810, EPA Reg. No. 29964-9) were registered February 24, 2010 with an expiration date of October 31, 2010. As part of the Agency's public participation initiative, the Agency provided for a concurrent public comment period which closed March 28, 2010. During this comment period, the Agency received several comments on these products. These comments and comments pertinent to these registrations submitted as part of the 2010 Bt Corn Reassessment comment period will be addressed separately, by the October 31, 2010 expiration date.

II. Cry 3Bb1 BRAD Registered Products

Registrant	Registration #	Active Ingredient	Original Registration Date	Status
Monsanto	524-528	<i>Bt</i> Corn Event MON863 with Cry3Bb1 (YieldGard® Rootworm)	24 February 2003	Cancelled (Expired on 30 September 2010)

Monsanto did not request an extension to their Corn Event MON 863 registration (EPA Reg. No. 524-528); therefore, this registration expired on its own terms on September 30, 2010. The Agency considers the expiration of a conditional, time-limited registration to be a cancellation under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A cancellation order, effective September 30, 2010, and appropriate provisions for disposition of existing stocks published in the Federal Register on August 25, 2010 ([75 FR 52329](#))

Registrant	Registration #	Active Ingredient	Original Registration Date	Status
Monsanto	524-545	<i>Bt</i> Corn Stack Event MON 863 + MON 819 with Cry3Bb1 + Cry1Ab (YieldGard® Plus)	31 October 2003	Cancelled (Expired on 30 September 2010)

Monsanto did not request an extension to their MON 863 x MON 810 registration (EPA Reg. No. 524-545); therefore, this registration expired on its own terms on September 30, 2010. The Agency considers the expiration of a conditional, time-limited registration to be a cancellation under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A cancellation order, effective September 30, 2010, and appropriate provisions for disposition of existing stocks published in the Federal Register on August 25, 2010 ([75 FR 52329](#)).

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Monsanto	524-551	<i>Bt</i> Corn Event MON 88017 with Cry3Bb1 (YieldGard VT Rootworm/RR2®)	13 December 2005	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Cry3Bb1 [*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)] for use in field and sweet corn. Further, MON 88017 sweet corn must only be used for breeding and testing purposes to produce MON 89034 x MON 88017 sweet corn seed.
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4] This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5] You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements relating to creation of a non-(corn rootworm-protected PIP) corn refuge in conjunction with the planting of any acreage of commercial MON 88017 corn.
 - Requirements for Monsanto Company (Monsanto) to prepare and require MON 88017 users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
 - Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
 - Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
 - Requirements for Monsanto to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry3Bb1 protein in the target insects.

- Requirements for Monsanto to develop, and if triggered, to implement a remedial action plan that would contain measures Monsanto would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for Monsanto, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to EPA upon request), IRM grower agreement results, and the compliance assurance program, including the education program.
- Requirements for Monsanto, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for MON 88017

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to MON 88017 sweet corn, used only for breeding and testing purposes to produce MON 89034 x MON 88017 sweet corn seed.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bacillus thuringiensis* (*Bt*) corn products, additional educational material and assistance will be provided by Monsanto to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-corn rootworm-protected corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply corn rootworm-labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the MON 88017 field is treated in a similar manner.
- Refuge planting options include the following: adjacent blocks, perimeter strips, or in-field strips.
- If blocks are implemented, they must be planted adjacent (e.g., across the road) to the MON 88017 field.
- If perimeter or in-field strips are implemented, the strips must be at least four (4) consecutive rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults

cannot be applied while adults are present in the refuge unless the MON 88017 field is treated in a similar manner.

- If the refuge is planted in a field that is in a crop rotation system, then MON 88017 must also be planted in a field that is in a crop rotation system.
- If the refuge is planted on continuous corn, then the MON 88017 field may be planted on either continuous corn or in a field that is in a crop rotation system.

b. Post-Harvest Requirements for MON 88017 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as part of the IRM program for sweet corn. For MON 88017 sweet corn, which is planted only for breeding and testing purposes to produce MON 89034 x MON 88017 sweet corn seed, the following crop destruction practices must be implemented:

- Crop destruction must occur no later than thirty (30) days following harvest.
- The allowed crop destruction methods are rotary mowing, discing, or plow down. These methods should destroy any surviving resistant insects.

c. Grower Agreements for MON 88017

1] Persons purchasing MON 88017 must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.

2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 88017 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4] Monsanto must continue to use its current grower agreement for MON 88017. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5] Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that

persons purchasing MON 88017 sign grower agreement(s).

6] Monsanto shall maintain records of all MON 88017 grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

7] Annually, Monsanto shall provide EPA with a report showing the number of units of MON 88017 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the 12-month period covering the prior August through July.

8] Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

d. IRM Education and Compliance Monitoring Programs for MON 88017

1] Monsanto must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to MON 88017 users the importance of complying with the IRM program. The program shall include information encouraging MON 88017 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 88017 fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 88017 user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4] Monsanto must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 88017 are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Monsanto's *Bt* corn products. Monsanto shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended

registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5] Monsanto must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to Monsanto's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 88017 who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

- i. A third party is classified as a party other than Monsanto, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with EPA prior to adopting any changes.

11] Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with MON 88017 growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12] Monsanto shall carry out a program for investigating legitimate tips and complaints that MON 88017 growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its phased compliance approach.

13] If a grower, who purchases MON 88017 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14] Annually, Monsanto shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Monsanto shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15] Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16] Monsanto shall revise and expand its existing compliance assurance program to include the following elements. Monsanto must prepare and submit, on or before January 31, 2011, a written description of its revised compliance assurance program. Monsanto may coordinate with other registrants in designing and implementing its compliance assurance program.

17] Monsanto will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all MON 88017 seed bags or bag tags. The MON 88017 label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over

the next three (3) growing seasons. Revised MON 88017 labels must be submitted by January 31, 2011, 50% implementation on the MON 88017 seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] Monsanto will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where MON 88017 is used.

19] Monsanto will use its available MON 88017 sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased MON 88017 but may have purchased little or no refuge seed from Monsanto, licensees, or affiliated companies.

20] Monsanto will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

21] Annually, Monsanto will refine the on-farm assessment program for MON 88017 to reflect the adoption rate and level of refuge compliance for MON 88017.

22] Monsanto will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two (2) years by Monsanto, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Monsanto will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for MON 88017 within a 5-year period will be denied access to Monsanto's *Bt* corn products the next year.

e. Insect Resistance Monitoring and Remedial Action Plan for MON 88017

EPA is imposing the following conditions for the Cry3Bb1 toxin expressed in MON 88017:

- 1] Monsanto must monitor for Cry3Bb1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- 2] The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.
- 3] Monsanto must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season, with reporting in 2012. As part of this effort, Monsanto must investigate the feasibility of using the Sublethal Seedling Assay¹ as a diagnostic assay. A report of Monsanto's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.
- 4] Monsanto must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to Cry3Bb1. As part of the effort, Monsanto may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Monsanto's progress towards this requirement must be submitted within one (1) year from the date of this amended registration.
- 5] Monsanto must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry3Bb1 within six (6) months from the date of this amended registration.
- 6] Monsanto must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.
- 7] Monsanto must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.
- 8] The current remedial action plan approved for Cry3Bb1 must be used for corn rootworm suspected and confirmed resistance in MON 88017. If corn rootworm resistance is confirmed, all acres of MON 88017 and refuges must be treated with insecticides targeted at corn rootworm adults and larvae.

¹ Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188.

f. Annual Reporting Requirements for MON 88017

- 1] Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2] Grower Agreement Results: number of units of MON 88017 seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3] Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.
- 4] Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5] Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Monsanto	524-552	<i>Bt</i> Corn Event MON 88017 + MON 810 with Cry3Bb1 + Cry1Ab (YieldGard VT Triple®)	13 December 2005	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Cry3Bb1 [*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)] x Cry1Ab [*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (vector PV-ZMCT01) in event MON 810 corn (OECD Unique Identifier: MON-ØØ81Ø-6)] for use in field corn.
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4] Submit/cite all data, determined by the Agency to be acceptable and required to support the individual plant-incorporated protectants in MON 88017 and MON 810, within the time frames required by the terms and conditions of EPA Registration Numbers 524-551 and 524-489, respectively.
- 5] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 6] You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements relating to creation of a refuge for the Cry3Bb1 and Cry1Ab components that meets the requirements of the individual traits. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1Ab component, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry3Bb1 component.
 - Requirements for Monsanto Company (Monsanto) to prepare and require MON 88017 x MON 810 users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
 - Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements.

- Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
- Requirements for Monsanto to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry3Bb1 and Cry1Ab proteins in the target insects.
- Requirements for Monsanto to develop, and if triggered, to implement a remedial action plan that would contain measures Monsanto would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for Monsanto, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program, including the education program.
- Requirements for Monsanto, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for MON 88017 x MON 810

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by Monsanto to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

Corn Belt/Non-Cotton-Growing Area Refuge Requirements

For MON 88017 x MON 810 grown in non-cotton-growing areas of the United States, two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of MON 88017 x MON 810 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the MON 88017 x MON 810 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge

can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the MON 88017 x MON 810 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of MON 88017 x MON 810 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 88017 x MON 810 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using method recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of MON 88017 x MON 810 acres and corn rootworm refuge acres), and must be planted as a block within or adjacent to the MON 88017 x MON 810 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the MON 88017 x MON 810 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Corn/Cotton-Growing Area (Cotton-Growing Area) Refuge Requirements

For MON 88017 x MON 810 grown in cotton-growing areas, the common refuge and separate refuge options are also available; however, the refuge area is larger. Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the

control of corn borers or corn rootworms. The refuge area must represent at least 50% of the grower's corn acres (i.e., sum of MON 88017 x MON 810 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the MON 88017 x MON 810 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the MON 88017 x MON 810 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 50% of the grower's corn acres (i.e., sum of MON 88017 x MON 810 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 88017 x MON 810 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of MON 88017 x MON 810 acres and corn rootworm refuge acres), and must be planted as a block within or adjacent to the MON 88017 x MON 810 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the MON 88017 x MON 810 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

b. Grower Agreements for MON 88017 x MON 810

- 1] Persons purchasing MON 88017 x MON 810 must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 88017 x MON 810 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4] Monsanto must continue to use its current grower agreement for MON 88017 x MON 810. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5] Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 88017 x MON 810 sign grower agreement(s).

6] Monsanto shall maintain records of all MON 88017 x MON 810 grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

7] Annually, Monsanto shall provide EPA with a report showing the number of units of MON 88017 x MON 810 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the 12-month period covering the prior August through July.

8] Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

c. IRM Education and Compliance Monitoring Programs for MON 88017 x MON 810

1] Monsanto must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to MON 88017 x MON 810 users the importance of complying with the IRM program. The program shall include information encouraging MON 88017 x MON 810 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 88017 x MON 810 fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 88017 x MON 810 user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6–8

of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4] Monsanto must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 88017 x MON 810 are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Monsanto's *Bt* corn products. Monsanto shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5] Monsanto must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to Monsanto's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 88017 x MON 810 who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

- i. A third party is classified as a party other than Monsanto, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA, on or before January 31st of each year. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with EPA prior to adopting any changes.

11] Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with MON 88017 x MON 810 growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12] Monsanto shall carry out a program for investigating legitimate tips and complaints that MON 88017 x MON 810 growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its phased compliance approach.

13] If a grower, who purchases MON 88017 x MON 810 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14] Annually, Monsanto shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Monsanto shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15] Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate

that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16] Monsanto shall revise and expand its existing compliance assurance program to include the following elements. Monsanto must prepare and submit, on or before January 31, 2011, a written description of its revised compliance assurance program. Monsanto may coordinate with other registrants in designing and implementing its compliance assurance program.

17] Monsanto will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all MON 88017 x MON 810 seed bags or bag tags. The MON 88017 x MON 810 label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three (3) growing seasons. Revised MON 88017 x MON 810 labels must be submitted by January 31, 2011, 50% implementation on the MON 88017 x MON 810 bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] Monsanto will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where MON 88017 x MON 810 is used.

19] Monsanto will use its available MON 88017 x MON 810 sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased MON 88017 x MON 810 but may have purchased little or no refuge seed from Monsanto, licensees, or affiliated companies.

20] Monsanto will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.

21] Annually, Monsanto will refine the on-farm assessment program for MON 88017 x MON

810 to reflect the adoption rate and level of refuge compliance for MON 88017 x MON 810.

22] Monsanto will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Monsanto, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Monsanto will conduct follow-up checks on growers found to be significantly out of compliance within 3 years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for MON 88017 x MON 810 within a 5-year period will be denied access to Monsanto's *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plans for MON 88017 x MON 810

1] EPA is imposing the following conditions for the Cry3Bb1 toxin expressed in MON 88017 x MON 810:

- i. Monsanto must monitor for Cry3Bb1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- ii. The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.
- iii. Monsanto must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season, with reporting in 2012. As part of this effort, Monsanto must investigate the feasibility of using the Sublethal Seedling Assay¹ as a diagnostic assay. A report of Monsanto's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.
- iv. Monsanto must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to Cry3Bb1. As part of the effort, Monsanto may need to investigate novel techniques for rearing and conducting bioassays with northern corn

¹ Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188.

rootworm. A report on Monsanto's progress towards this requirement must be submitted within one (1) year from the date of this amended registration.

- v. Monsanto must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry3Bb1 within six (6) months from the date of this amended registration.
- vi. Monsanto must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. Monsanto must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.
- viii. The current remedial action plan approved for Cry3Bb1 must be used for corn rootworm suspected and confirmed resistance in MON 88017 x MON 810. If corn rootworm resistance is confirmed, all acres of MON 88017 x MON 810 and refuges must be treated with insecticides targeted at CRW adults and larvae.

2] EPA is imposing the following conditions for the Cry1Ab toxin expressed in MON 88017 x MON 810:

Monsanto will monitor for resistance to Cry1Ab expressed in MON 88017 x MON 810. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

Focused Population Sampling

Monsanto shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 88017 x MON 810 and/or changes in resistance allele frequency in response to the use of MON 88017 x MON 810 and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of twelve (12) populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six (6) populations. For CEW, the target will be a minimum of ten (10) populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect

genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 88017 x MON 810. EPA shall be consulted prior to the implementation of such modifications.

Monsanto will report to EPA, on or before August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1Ab protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before August 31st. The investigative steps will include the following:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 88017 x MON 810 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:

- determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
- estimating the resistance allele frequency in the original population;
- determining whether the resistance allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with EPA to develop and implement a case-specific resistance management action plan.

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

Monsanto will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected Resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect-feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 88017 x MON 810 in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 88017 x MON 810 fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 88017 x MON 810 crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed Resistance

EPA defines ***confirmed resistance*** to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is ***confirmed*** (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;
- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs.

Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before August 31st each year, for the duration of the registration.

e. Annual Reporting Requirements for MON 88017 x MON 810

- 1] Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2] Grower Agreement Results: number of units of MON 88017 x MON 810 seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3] Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.
- 4] Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5] Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

III. Cry 34Ab1/Cry35Ab1 BRAD Registered Products

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Mycogen Seeds c/o Dow AgroSciences	68467-5	<i>Bt</i> Corn Event DAS-59122-7 with Cry 34/35Ab1 (Herculex® RW Insect Protection)	31 August 2005	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Cry34Ab1 and Cry35Ab1 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (PHP17662 T-DNA) in event DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7)] for use in field corn.
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4] This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5] Should you wish to amend the refuge treatment option to allow independent treatment of the refuge for pests other than corn rootworms, data would be required regarding the impact of independent treatment of the refuge for other pests (not corn rootworm, e.g., corn borers, spider mites) on corn rootworm resistance management.
- 6] You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements relating to creation of a non-(corn rootworm-protected PIP) corn refuge in conjunction with the planting of any acreage of commercial Herculex® RW Insect Protection corn.
 - Requirements for Mycogen Seeds c/o Dow AgroSciences LLC (DAS) to prepare and require Herculex® RW Insect Protection corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
 - Requirements for DAS to develop, implement, and report to EPA on programs to educate growers about IRM requirements.

- Requirements for DAS to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
- Requirements for DAS to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry34Ab1 and Cry35Ab1 proteins in the target insects.
- Requirements for DAS to develop, and if triggered, to implement a remedial action plan that would contain measures DAS would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for DAS, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to EPA upon request), IRM grower agreements results, and the compliance assurance program, including the education program.
- Requirements for DAS, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for Herculex® RW Insect Protection Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bacillus thuringiensis* (Bt) corn products, additional educational material and assistance are provided by DAS to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

1) *Refuge size.* The use of Herculex® RW Insect Protection corn from event DAS-59122-7 requires an accompanying 20% refuge.

2) *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® RW Insect Protection corn field.

3) *Refuge management options.* The rootworm refuge may be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.

- The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.

- Seed mixtures of Herculex® RW Insect Protection and refuge corn are not permitted.
- If the refuge is planted on rotated ground, then Herculex® RW Insect Protection corn must also be planted on rotated ground.
- If the refuge is planted in continuous corn, the Herculex® RW Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
- Application of soil insecticide is permitted in the refuge.
- Seed treatment is permitted in the refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® RW Insect Protection corn.
- Pests other than adult corn rootworms may only be treated with corn rootworm-labeled insecticides on the refuge acres without treating the Herculex® RW Insect Protection corn acres if treatment occurs when adult corn rootworms are not present. Pests on the Herculex® RW Insect Protection corn acres may be treated as needed without having to treat the refuge.
- The rootworm refuge may be planted to any corn hybrid that does not express plant-incorporated protectants for rootworm control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The refuge and Herculex® RW Insect Protection corn should be sown on the same date, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn; however, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

b. Grower Agreements for Herculex® RW Insect Protection Corn

- 1] Persons purchasing Herculex® RW Insect Protection corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM

program.

3] DAS must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® RW Insect Protection corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4] DAS must continue to use its current grower agreement for Herculex® RW Insect Protection corn. If DAS wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, DAS must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5] DAS must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® RW Insect Protection corn sign grower agreement(s).

6] DAS shall maintain records of all Herculex® RW Insect Protection corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

7] Annually, DAS shall provide EPA with a report showing the number of units of Herculex® RW Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the 12-month period covering the prior August through July.

8] DAS must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

c. IRM Education and Compliance Monitoring Programs for Herculex® RW Insect Protection Corn

1] DAS must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Herculex® RW Insect Protection corn users the importance of complying with the IRM program. The program shall include information encouraging Herculex® RW Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Herculex® RW Insect Protection corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Herculex® RW Insect Protection corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. DAS shall coordinate its education programs

with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, DAS shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, DAS must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. DAS must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4] DAS must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Herculex® RW Insect Protection corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to DAS' *Bt* corn products. DAS shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5] DAS must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, DAS must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to DAS' *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of Herculex® RW Insect Protection corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

- i. A third party is classified as a party other than DAS, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] DAS shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. DAS shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, DAS shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. DAS must confer with EPA prior to adopting any changes.

11] DAS shall conduct an annual on-farm assessment program. DAS shall train its representatives who make on-farm visits with Herculex® RW Insect Protection corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, DAS shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12] DAS shall carry out a program for investigating legitimate tips and complaints that Herculex® RW Insect Protection corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, DAS shall take appropriate action, consistent with its phased compliance approach.

13] If a grower, who purchases Herculex® RW Insect Protection corn for planting, was specifically identified as not being in compliance during the previous year, DAS shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14] Annually, DAS shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, DAS shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. DAS may elect to coordinate information with other registrants and report collectively the results of compliance assurance

programs.

15] DAS and the seed corn dealers for DAS must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16] DAS shall revise and expand its existing compliance assurance program to include the following elements. DAS must prepare and submit, on or before January 31, 2011, a written description of its revised compliance assurance program. DAS may coordinate with other registrants in designing and implementing its compliance assurance program.

17] DAS will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all Herculex® RW Insect Protection corn seed bags or bag tags. The Herculex® RW Insect Protection corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three (3) growing seasons. Revised Herculex® RW Insect Protection corn labels must be submitted by January 31, 2011, 50% implementation on the Herculex® RW Insect Protection corn bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] DAS will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Herculex® RW Insect Protection corn is used.

19] DAS will use its available Herculex® RW Insect Protection corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Herculex® RW Insect Protection corn but may have purchased little or no refuge seed from DAS, licensees, or affiliated companies.

20] DAS will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

21] Annually, DAS will refine the on-farm assessment program for Herculex® RW Insect Protection corn to reflect the adoption rate and level of refuge compliance for Herculex® RW Insect Protection corn.

22] DAS will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by DAS, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. DAS will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Herculex® RW Insect Protection corn within a 5-year period will be denied access to DAS' *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan for Herculex® RW Insect Protection Corn

EPA is imposing the following conditions for the Cry34Ab1 and Cry35Ab1 toxins expressed in Herculex® RW Insect Protection corn:

- 1] DAS must monitor for Cry34/35Ab1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- 2] The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.
- 3] DAS must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season, with reporting in 2012. As part of this effort, DAS must investigate the feasibility of using the Sublethal Seedling Assay¹ as a diagnostic assay. A

¹ Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188.

report of DAS' progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.

4] DAS must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to Cry34/35Ab1. As part of the effort, DAS may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on DAS' progress towards this requirement must be submitted within one (1) year from the date of this amended registration.

5] DAS must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry34/35Ab1 within six (6) months from the date of this amended registration.

6] DAS must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.

7] DAS must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.

8] The remedial action plan is designed as a tiered approach for mitigating *Diabrotica virgifera virgifera* (western corn rootworm; WCRW), *Diabrotica barberi* (northern corn rootworm; NCRW), and *Diabrotica virgifera zea* (Mexican corn rootworm; MCRW) resistance development to the Cry34Ab1 and Cry35Ab1 proteins. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to the target pests is confirmed.

Definition of Suspected Resistance

Resistance will be ***suspected*** if investigations of unexpected damage reports show the following:

- i. implicated corn plant roots were expressing the Cry34Ab1 and Cry35Ab1 proteins at the expected levels;
- ii. the seed used was not mixed with non-Cry34/35Ab1 seed;
- iii. alternative causes of damage or lodging, such as nontarget pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out; and
- iv. the level of damage exceeds guidelines for expected damage.

If resistance is ***suspected***, DAS will instruct affected growers to use alternate pest control measures, such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

Confirmation of Resistance

Resistance will be **confirmed** if all of the following criteria are met by progeny from the target pest species sampled from the area of **suspected resistance**:

- i. the proportion of larvae that can feed and survive on Herculex® RW Insect Protection corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
- ii. the LC_{50} of the test population exceeds the upper limit of the 95% confidence interval for the LC_{50} of a standard unselected population, and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
- iii. the ability to survive is heritable;
- iv. Herculex® RW Insect Protection corn plant assays determine that damage caused by surviving insects would exceed economic thresholds; and
- v. if subsequent collections in the affected field area demonstrate similar bioassay results.

Response to Confirmed Resistance

When resistance is **confirmed**, the following steps will be taken:

- i. EPA will receive notification within 30 days of confirming resistance;
- ii. affected customers and extension agents will be notified about confirmed resistance;
- iii. affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures;
- iv. sale and distribution of Herculex® RW Insect Protection corn in the affected area will cease immediately; and
- v. a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs.

e. Annual Reporting Requirements for Herculex® RW Insect Protection Corn

1] Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.

2] Grower Agreement Results: number of units of Herculex® RW Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.

- 3] Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.
- 4] Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5] Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer Hi-Bred International, Incorporated	29964-4	<i>Bt</i> Corn Event DAS-59122-7 with Cry34/35Ab1 (Herculex® Rootworm Insect Protection)	31 August 2005	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Cry34Ab1 and Cry35Ab1 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (PHP17662 T-DNA) in event DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7)] for use in field corn.
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4] This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5] Should you wish to amend the refuge treatment option to allow independent treatment of the refuge for pests other than corn rootworms, data would be required regarding the impact of independent treatment of the refuge for other pests (not corn rootworm, e.g., corn borers, spider mites) on corn rootworm resistance management.
- 6] You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements relating to creation of a non-(corn rootworm-protected PIP) corn refuge in conjunction with the planting of any acreage of commercial Herculex® Rootworm Insect Protection corn.
 - Requirements for Pioneer Hi-Bred International, Incorporated (Pioneer) to prepare and require Herculex® Rootworm Insect Protection corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
 - Requirements for Pioneer to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
 - Requirements for Pioneer to develop, implement, and report to EPA on programs to

evaluate and promote growers' compliance with IRM requirements.

- Requirements for Pioneer to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry34Ab1 and Cry35Ab1 proteins in the target insects.
- Requirements for Pioneer to develop, and if triggered, to implement a remedial action plan that would contain measures Pioneer would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for Pioneer, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to EPA upon request), IRM grower agreements results, and the compliance assurance program, including the education program.
- Requirements for Pioneer, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for Herculex® Rootworm Insect Protection Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bacillus thuringiensis* (Bt) corn products, additional educational material and assistance will be provided by Pioneer to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

1] *Refuge size.* The use of Herculex® Rootworm Insect Protection corn from event DAS 59122-7 requires an accompanying 20% refuge.

2] *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® Rootworm Insect Protection corn field.

3] *Refuge management options.* The rootworm refuge may be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.

- The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.

- Seed mixtures of Herculex® Rootworm Insect Protection and refuge corn are not permitted.
- If the refuge is planted on rotated ground, then Herculex® Rootworm Insect Protection corn must also be planted on rotated ground.
- If the refuge is planted in continuous corn, the Herculex® Rootworm Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
- Application of soil insecticide is permitted in the refuge.
- Seed treatment is permitted in the refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® Rootworm Insect Protection corn.
- Pests other than adult corn rootworms can only be treated with corn rootworm-labeled insecticides on the refuge acres without treating the Herculex® Rootworm Insect Protection corn acres if treatment occurs when adult corn rootworms are not present. Pests on the Herculex® Rootworm Insect Protection corn acres can be treated as needed without having to treat the refuge.
- The rootworm refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for rootworm control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The refuge and Herculex® Rootworm Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn; however, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

b. Grower Agreements for Herculex® Rootworm Insect Protection Corn

- 1] Persons purchasing Herculex® Rootworm Insect Protection corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower

agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] Pioneer must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® Rootworm Insect Protection corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4] Pioneer must continue to use its current grower agreement for Herculex® Rootworm Insect Protection corn. If Pioneer wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5] Pioneer must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® Rootworm Insect Protection corn sign grower agreement(s).

6] Pioneer shall maintain records of all Herculex® Rootworm Insect Protection corn grower agreements for a period of 3 years from December 31st of the year in which the agreement was signed.

7] Annually, Pioneer shall provide EPA with a report showing the number of units of Herculex® Rootworm Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the 12-month period covering the prior August through July.

8] Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

c. IRM Education and Compliance Monitoring Programs for Herculex® Rootworm Insect Protection Corn

1] Pioneer must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Herculex® Rootworm Insect Protection corn users the importance of complying with the IRM program. The program shall include information encouraging Herculex® Rootworm Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Herculex® Rootworm Insect Protection corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Herculex® Rootworm Insect Protection corn user separate from the grower technical guide. The

communication shall inform the user of the current IRM requirements. Pioneer shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, Pioneer must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Pioneer must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4] Pioneer must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Herculex® Rootworm Insect Protection corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Pioneer's *Bt* corn products. Pioneer shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5] Pioneer must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Pioneer must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to Pioneer's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of Herculex® Rootworm Insect Protection corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

- i. A third party is classified as a party other than Pioneer, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Pioneer shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. Pioneer shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, Pioneer shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Pioneer must confer with EPA prior to adopting any changes.

11] Pioneer shall conduct an annual on-farm assessment program. Pioneer shall train its representatives who make on-farm visits with Herculex® Rootworm Insect Protection corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12] Pioneer shall carry out a program for investigating legitimate tips and complaints that Herculex® Rootworm Insect Protection corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its phased compliance approach.

13] If a grower, who purchases Herculex® Rootworm Insect Protection corn for planting, was specifically identified as not being in compliance during the previous year, Pioneer shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14] Annually, Pioneer shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Pioneer shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance

with the insect resistance management refuge requirements. Pioneer may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15] Pioneer and the seed corn dealers for Pioneer must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16] Pioneer shall revise and expand its existing compliance assurance program to include the following elements. Pioneer must prepare and submit, on or before January 31, 2011, a written description of its revised compliance assurance program. Pioneer may coordinate with other registrants in designing and implementing its compliance assurance program.

17] Pioneer will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all Herculex® Rootworm Insect Protection corn seed bags or bag tags. The Herculex® Rootworm Insect Protection corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three (3) growing seasons. Revised Herculex® Rootworm Insect Protection corn labels must be submitted by January 31, 2011, 50% implementation on the Herculex® Rootworm Insect Protection corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] Pioneer will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Herculex® Rootworm Insect Protection corn is used.

19] Pioneer will use its available Herculex® Rootworm Insect Protection corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Herculex® Rootworm Insect Protection corn but may have purchased little or no refuge seed from Pioneer, licensees, or affiliated companies.

20] Pioneer will contract with third parties to perform on-farm assessments of compliance with

refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

21] Annually, Pioneer will refine the on-farm assessment program for Herculex® Rootworm Insect Protection corn to reflect the adoption rate and level of refuge compliance for Herculex® Rootworm Insect Protection corn.

22] Pioneer will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Pioneer, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Pioneer will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Herculex® Rootworm Insect Protection corn within a 5-year period will be denied access to Pioneer's *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan for Herculex® Rootworm Insect Protection Corn

EPA is imposing the following conditions for the Cry34Ab1 and Cry35Ab1 toxins expressed in Herculex® Rootworm Insect Protection corn:

1] Pioneer must monitor for Cry34/35Ab1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.

2] The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.

3] Pioneer must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season, with reporting in 2012. As part of this effort, Pioneer must investigate the feasibility of using the Sublethal Seedling Assay^{II} as a diagnostic assay. A

^{II} Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J.*

report of Pioneer's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.

4] Pioneer must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to Cry34/35Ab1. As part of the effort, Pioneer may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Pioneer's progress towards this requirement must be submitted within one (1) year from the date of this amended registration.

5] Pioneer must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry34/35Ab1 within six (6) months from the date of this amended registration.

6] Pioneer must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.

7] Pioneer must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.

8] The remedial action plan is designed as a tiered approach for mitigating *Diabrotica virgifera virgifera* (western corn rootworm; WCRW), *Diabrotica barberi* (northern corn rootworm; NCRW), and *Diabrotica virgifera zea* (Mexican corn rootworm; MCRW) resistance development to the Cry34Ab1 and Cry35Ab1 proteins. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to the target pests is confirmed.

Definition of Suspected Resistance

If resistance is "suspected", the registrants will instruct affected growers to use alternate pest control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

Resistance will be *suspected* if investigations of unexpected damage reports show the following:

- i. implicated corn plant roots were expressing the Cry34Ab1 and Cry35Ab1 proteins at the expected levels;
- ii. the seed used was not mixed with non-Cry34/35Ab1 seed;
- iii. alternative causes of damage or lodging, such as nontarget pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out; and

- iv. the level of damage exceeds guidelines for expected damage.

If resistance is **suspected**, Pioneer will instruct affected growers to use alternate pest control measures, such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

Confirmation of Resistance

Resistance will be **confirmed** if all of the following criteria are met by progeny from the target pest species sampled from the area of **suspected resistance**:

- i. the proportion of larvae that can feed and survive on Herculex® Rootworm Insect Protection corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
- ii. the LC_{50} of the test population exceeds the upper limit of the 95% confidence interval for the LC_{50} of a standard unselected population, and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
- iii. the ability to survive is heritable;
- iv. Herculex® Rootworm Insect Protection corn plant assays determine that damage caused by surviving insects would exceed economic thresholds; and
- v. if subsequent collections in the affected field area demonstrate similar bioassay results.

Response to Confirmed Resistance

When resistance is **confirmed**, the following steps will be taken:

- i. EPA will receive notification within 30 days of confirming resistance;
- ii. affected customers and extension agents will be notified about confirmed resistance;
- iii. affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures;
- iv. sale and distribution of Herculex® Rootworm Insect Protection corn in the affected area will cease immediately; and
- v. a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs.

e. Annual Reporting Requirements for Herculex® Rootworm Insect Protection Corn

- 1] Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2] Grower Agreement Results: number of units of Herculex® Rootworm Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3] Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.
- 4] Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5] Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.
- 6] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Mycogen Seeds c/o Dow AgroSciences	68467-6	<i>Bt</i> Corn Events DAS-59122-7 + TC1507 with Cry34Ab1/Cry35Ab1 + PO Cry1F (Herculex® XTRA Insect Protection)	27 October 2005	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999A) in event TC1507 corn (OECD Unique Identifier: DAS-Ø15Ø7-1)] x Cry34Ab1 and Cry35Ab1 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (PHP17662 T-DNA) in event DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7)] for use in field corn.
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4] Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants in Herculex® I Insect Protection and Herculex® RW Insect Protection, within the time frames required by the terms and conditions of EPA Registration Numbers 68467-2 and 68467-5, respectively.
- 5] This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 6] You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements relating to creation of a refuge for the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F component, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry34/35Ab1 component.
 - Requirements for Mycogen Seeds c/o Dow AgroSciences LLC (DAS) to prepare and require Herculex® XTRA Insect Protection corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.

- Requirements for DAS to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
- Requirements for DAS to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
- Requirements for DAS to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1F and Cry34/35Ab1 proteins in the target insects.
- Requirements for DAS to develop, and if triggered, to implement a remedial action plan that would contain measures DAS would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for DAS, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to EPA upon request), IRM grower agreement results, and the compliance assurance program, including the education program.
- Requirements for DAS, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for Herculex® XTRA Insect Protection Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by the registrant to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

The use of Herculex® XTRA Insect Protection corn requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits, as described below. The refuge for both traits may be combined by planting non-*Bt* corn as the refuge (see the "Combined Refuge Option" section), or the refuge for each trait may be planted separately (see the "Lepidopteran Refuge for the Cry1F Component" and "Corn Rootworm Refuge for the Cry34/35Ab1 Component" sections).

For the separate refuges, corn rootworm-resistant *Bt* corn (e.g., Herculex® RW Insect Protection) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran-resistant *Bt* corn (e.g., Herculex® I Insect Protection) may be planted in the corn

rootworm refuge for the Cry34/35Ab1 component. Depending on cropping practices, pest problems, and pest management options employed on any given farm, growers may need to choose different refuge arrangements for different fields. Two refuge blocks (one for rootworm, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of Herculex® RW Insect Protection corn can serve as an in-field lepidopteran refuge for one field planted to Herculex® XTRA Insect Protection corn and an external lepidopteran refuge for separate fields planted to Herculex® XTRA Insect Protection corn, while the rootworm refuge is planted as Herculex® I Insect Protection corn in an external adjacent field. In all options, size and management of each individual refuge must be followed as described in the “Lepidopteran Refuge for the Cry1F Component” and “Corn Rootworm Refuge for the Cry34/35Ab1 Component” sections.

Other refuge designs and combinations are permissible as long as, in all cases, the size and management of each refuge are described in the “Lepidopteran Refuge for the Cry1F Component,” “Corn Rootworm Refuge for the Cry34/35Ab1 Component,” or “Combined Refuge Option” sections.

Lepidopteran Refuge for the Cry1F Component

1] *Refuge size, Corn-growing areas (Corn Belt and other non-corn/cotton-growing areas).* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

2] **Refuge size, Corn/cotton-growing areas.* The use Herculex® XTRA Insect Protection corn requires an accompanying 50% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

3] *Refuge location.*

- The lepidopteran refuge can be planted in a separate field not more than ½ mile from the Herculex® XTRA Insect Protection corn field.
- The lepidopteran refuge can be planted within the Herculex® XTRA Insect Protection corn field as blocks (e.g., along the edges or headlands).
- The lepidopteran refuge can be planted within the Herculex® XTRA Insect Protection corn field as strips across the field at least four (4) consecutive rows wide.

4] *Refuge management.*

Insecticide treatment for European corn borer (ECB), corn earworm (CEW), southwestern corn borer (SWCB), and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one (1) or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

*Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Rootworm Refuge for the Cry34/35Ab1 Component

- 1] *Refuge size.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a rootworm-protected *Bt* hybrid.
- 2] *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA Insect Protection corn field.
- 3] *Refuge management options.* The rootworm refuge can be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.
 - The in-field rootworm refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
 - Seed mixtures of Herculex® XTRA Insect Protection and rootworm refuge corn are not permitted.
 - If the rootworm refuge is planted on rotated ground, then Herculex® XTRA Insect Protection corn must also be planted on rotated ground.
 - If the rootworm refuge is planted in continuous corn, the Herculex® XTRA Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
 - Application of soil insecticide is permitted in the rootworm refuge.
 - Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
 - If aerial insecticides are applied to the rootworm refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® XTRA Insect Protection corn.

- Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present or if pesticide without activity against adult corn rootworms is used. Pests on the Herculex® XTRA Insect Protection corn acres can be treated as needed without having to treat the rootworm refuge.
- The rootworm refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for rootworm control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The rootworm refuge and Herculex® XTRA Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn; however, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

Combined Refuge Option

For the combined refuge option (i.e. the lepidopteran refuge combined with the rootworm refuge by planting non-*Bt* corn), the refuge must be planted and managed such that it is consistent with the requirements of the two individual traits, Cry1F and Cry34/35Ab1.

1] *Refuge size.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge in corn-growing areas and 50% refuge in cotton-growing areas consisting of non-*Bt* corn. For the latter, see the list of states labeled with “*” in the “Lepidopteran Refuge for the Cry1F Component” section.

2] *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA Insect Protection corn field.

3] *Refuge management options.*

- The in-field combined refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
- Seed mixtures of Herculex® XTRA Insect Protection and combined refuge corn are not permitted.
- If the combined refuge is planted on rotated ground, then Herculex® XTRA Insect Protection corn must also be planted on rotated ground.

- If the combined refuge is planted in continuous corn, the Herculex® XTRA Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
- Application of soil insecticide for corn rootworm control is permitted in the combined refuge.
- Seed treatment is permitted in the combined refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the combined refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® XTRA Insect Protection corn.
- Insecticide treatments in the combined refuge for control of ECB, CEW, SWCB, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one (1) or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). These pests can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.
- Pests other than adult corn rootworms can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Herculex® XTRA Insect Protection corn acres can be treated as needed without having to treat the combined refuge.
- The combined refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for lepidopteran or rootworm control (i.e., herbicide-tolerant corn or conventional corn).
- The combined refuge and Herculex® XTRA Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.

b. Grower Agreements for Herculex® XTRA Insect Protection Corn

- 1] Persons purchasing Herculex® XTRA Insect Protection corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower

agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] DAS must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® XTRA Insect Protection corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4] DAS must continue to use its current grower agreement for Herculex® XTRA Insect Protection corn. If DAS wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, DAS must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5] DAS must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® XTRA Insect Protection corn sign grower agreement(s).

6] DAS shall maintain records of all Herculex® XTRA Insect Protection corn grower agreements for a period of 3 years from December 31st of the year in which the agreement was signed.

7] Annually, DAS shall provide EPA with a report showing the number of units of Herculex® XTRA Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the 12-month period covering the prior August through July.

8] DAS must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

c. IRM Education and Compliance Monitoring Programs for Herculex® XTRA Insect Protection Corn

1] DAS must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Herculex® XTRA Insect Protection corn users the importance of complying with the IRM program. The program shall include information encouraging Herculex® XTRA Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Herculex® XTRA Insect Protection corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each

Herculex® XTRA Insect Protection corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. DAS shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, DAS shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, DAS must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. DAS must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4] DAS must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Herculex® XTRA Insect Protection corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to DAS' *Bt* corn products. DAS shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5] DAS must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, DAS must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to DAS' *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of Herculex® XTRA Insect Protection corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

- i. A third party is classified as a party other than DAS, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] DAS shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. DAS shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, DAS shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. DAS must confer with EPA prior to adopting any changes.

11] DAS shall conduct an annual on-farm assessment program. DAS shall train its representatives who make on-farm visits with Herculex® XTRA Insect Protection corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, DAS shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12] DAS shall carry out a program for investigating legitimate tips and complaints that Herculex® XTRA Insect Protection corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, DAS shall take appropriate action, consistent with its phased compliance approach.

13] If a grower, who purchases Herculex® XTRA Insect Protection corn for planting, was specifically identified as not being in compliance during the previous year, DAS shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14] Annually, DAS shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, DAS shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of

growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. DAS may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15] DAS and the seed corn dealers for DAS must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16) DAS shall revise and expand its existing compliance assurance program to include the following elements. DAS must prepare and submit, on or before January 31, 2011, a written description of its revised compliance assurance program. DAS may coordinate with other registrants in designing and implementing its compliance assurance program.

17) DAS will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all Herculex® XTRA Insect Protection corn seed bags or bag tags. The Herculex® XTRA Insect Protection corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three (3) growing seasons. Revised Herculex® XTRA Insect Protection corn labels must be submitted by January 31, 2011, 50% implementation on the Herculex® XTRA Insect Protection corn bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18) DAS will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Herculex® XTRA Insect Protection corn is used.

19] DAS will use its available Herculex® XTRA Insect Protection corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Herculex® XTRA Insect Protection corn but may have purchased little or no refuge seed from DAS, licensees, or affiliated companies.

20] DAS will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

21] Annually, DAS will refine the on-farm assessment program for Herculex® XTRA Insect Protection corn to reflect the adoption rate and level of refuge compliance for Herculex® XTRA Insect Protection corn.

22] DAS will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two (2) years by DAS, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. DAS will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Herculex® XTRA Insect Protection corn within a 5-year period will be denied access to DAS' *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan for Herculex® XTRA Insect Protection Corn

1] EPA is imposing the following conditions for the Cry1F toxin expressed in Herculex® XTRA Insect Protection corn:

DAS will monitor for resistance to Cry1F expressed in Herculex® XTRA Insect Protection corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

Focused Population Sampling

DAS shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to Herculex® XTRA Insect Protection corn

and/or changes in resistance allele frequency in response to the use of Herculex® XTRA Insect Protection corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of twelve (12) populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six (6) populations. For CEW, the target will be a minimum of ten (10) populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Herculex® XTRA Insect Protection corn. EPA shall be consulted prior to the implementation of such modifications.

DAS will report to EPA, on or before August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1F protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before August 31st. The investigative steps will include the following:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Herculex® XTRA Insect Protection corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:
 - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
 - estimating the resistance allele frequency in the original population;

- determining whether the resistance allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, DAS will consult with EPA to develop and implement a case-specific resistance management action plan.

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

DAS will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. DAS will instruct its customers to contact them if such incidents occur. DAS will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), DAS will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected Resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect-feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Herculex® XTRA Insect Protection corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, DAS will instruct growers to do the following:

- Use alternative control measures in Herculex® XTRA Insect Protection corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Herculex® XTRA Insect Protection corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, DAS will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed Resistance

EPA defines ***confirmed resistance*** to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is ***confirmed*** (as defined above), the following steps will be taken by DAS:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control

target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;
- DAS will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. DAS will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before August 31st of each year, for the duration of the registration.

2) EPA is imposing the following conditions for the Cry34Ab1 and Cry35Ab1 toxins expressed in Herculex® XTRA Insect Protection corn:

- i. DAS must monitor for Cry34/35Ab1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- ii. The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.
- iii. DAS must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season, with reporting in 2012. As part of this effort, DAS must investigate the feasibility of using the Sublethal Seedling Assay^{III} as a diagnostic assay. A report of DAS' progress towards this

^{III} Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J.*

- requirement must be submitted to EPA within six (6) months from the date of this amended registration.
- iv. DAS must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to Cry34/35Ab1. As part of the effort, DAS may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on DAS' progress towards this requirement must be submitted within one (1) year from the date of this amended registration.
 - v. DAS must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry34/35Ab1 within six (6) months from the date of this amended registration.
 - vi. DAS must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.
 - vii. DAS must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.
 - viii. The remedial action plan is designed as a tiered approach for mitigating *Diabrotica virgifera virgifera* (western corn rootworm; WCRW), *Diabrotica barberi* (northern corn rootworm; NCRW), and *Diabrotica virgifera zea* (Mexican corn rootworm; MCRW) resistance development to the Cry34Ab1 and Cry35Ab1 proteins. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to the target pests is confirmed.

Definition of Suspected Resistance

Resistance will be ***suspected*** if investigations of unexpected damage reports show the following:

- i. implicated corn plant roots were expressing the Cry34Ab1 and Cry35Ab1 proteins at the expected levels;
- ii. the seed used was not mixed with non-Cry34/35Ab1 seed;
- iii. alternative causes of damage or lodging, such as nontarget pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out; and
- iv. the level of damage exceeds guidelines for expected damage.

If resistance is *suspected*, DAS will instruct affected growers to use alternate pest control measures, such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

Confirmation of Resistance

Resistance will be *confirmed* if all of the following criteria are met by progeny from the target pest species sampled from the area of *suspected resistance*:

- i. the proportion of larvae that can feed and survive on Herculex® XTRA Insect Protection corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
- ii. the LC₅₀ of the test population exceeds the upper limit of the 95% confidence interval for the LC₅₀ of a standard unselected population, and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
- iii. the ability to survive is heritable;
- iv. Herculex® XTRA Insect Protection corn plant assays determine that damage caused by surviving insects would exceed economic thresholds; and
- v. if subsequent collections in the affected field area demonstrate similar bioassay results.

Response to Confirmed Resistance

When resistance is *confirmed*, the following steps will be taken:

- i. EPA will receive notification within 30 days of confirming resistance;
- ii. affected customers and extension agents will be notified about confirmed resistance;
- iii. affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures;
- iv. sale and distribution of Herculex® XTRA Insect Protection corn in the affected area will cease immediately; and
- v. a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs.

e. Annual Reporting Requirements for Herculex® XTRA Insect Protection Corn

- 1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2) Grower Agreement Results: number of units of Herculex® XTRA Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3) Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.
- 4) Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5) Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer Hi-Bred International, Incorporated	29964-5	<i>Bt</i> Corn Events DAS-59122-7 + TC1507 with Cry34Ab1/Cry35Ab1 + PO Cry1F (Herculex XTRA® Insect Protection)	27 October 2005	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHP8999A) in event TC1507 corn (OECD Unique Identifier: DAS-Ø15Ø7-1)] x Cry34Ab1 and Cry35Ab1 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (PHP17662 T-DNA) in event DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7)] for use in field corn.
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4] Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants in Herculex® I Insect Protection and Herculex® Rootworm Insect Protection, within the time frames required by the terms and conditions of EPA Registration Numbers 29964-3 and 29964-4, respectively.
- 5] This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 6] You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements relating to creation of a refuge for the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F component, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry34/35Ab1 component.
 - Requirements for Pioneer Hi-Bred International, Incorporated (Pioneer) to prepare and require Herculex® XTRA Insect Protection corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge

requirements.

- Requirements for Pioneer to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
- Requirements for Pioneer to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
- Requirements for Pioneer to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1F and Cry34/35Ab1 proteins in the target insects.
- Requirements for Pioneer to develop, and if triggered, to implement a remedial action plan that would contain measures Pioneer would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for Pioneer, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to EPA upon request), IRM grower agreement results, and the compliance assurance program, including the education program.
- Requirements for DAS, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for Herculex® XTRA Insect Protection Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Pioneer to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

The use of Herculex® XTRA Insect Protection corn requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits, as described below. The refuge for both traits may be combined by planting non-*Bt* corn as the refuge (see the "Combined Refuge Option" section), or the refuge for each trait may be planted separately (see the "Lepidopteran Refuge for the Cry1F Component" and "Corn Rootworm Refuge for the Cry34/35Ab1 Component" sections).

For the separate refuges, corn rootworm-resistant *Bt* corn (e.g., Herculex® Rootworm Insect Protection) may be planted in the lepidopteran refuge for the Cry1F component, and

lepidopteran-resistant *Bt* corn (e.g., Herculex® I Insect Protection) may be planted in the corn rootworm refuge for the Cry34/35Ab1 component. Depending on cropping practices, pest problems, and pest management options employed on any given farm, growers may need to choose different refuge arrangements for different fields. Two refuge blocks (one for rootworm, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of Herculex® Rootworm Insect Protection corn can serve as an in-field lepidopteran refuge for one field planted to Herculex® XTRA Insect Protection corn and an external lepidopteran refuge for separate fields planted to Herculex® XTRA Insect Protection corn, while the rootworm refuge is planted as Herculex® I Insect Protection corn in an external adjacent field. In all options, size and management of each individual refuge must be followed as described in the “Lepidopteran Refuge for the Cry1F Component” and “Corn Rootworm Refuge for the Cry34/35Ab1 Component” sections.

Other refuge designs and combinations are permissible as long as, in all cases, the size and management of each refuge are described in the “Lepidopteran Refuge for the Cry1F Component,” “Corn Rootworm Refuge for the Cry34/35Ab1 Component,” or “Combined Refuge Option” sections.

Lepidopteran Refuge for the Cry1F Component

1] *Refuge size, Corn-growing areas (Corn Belt and other non-corn/cotton-growing areas).* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

2] **Refuge size, Corn/cotton-growing areas.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 50% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

3] *Refuge location.*

- The lepidopteran refuge can be planted in a separate field not more than ½ mile from the Herculex® XTRA Insect Protection corn field.
- The lepidopteran refuge can be planted within the Herculex® XTRA Insect Protection corn field as blocks (e.g., along the edges or headlands).
- The lepidopteran refuge can be planted within the Herculex® XTRA Insect Protection corn field as strips across the field at least four (4) consecutive rows wide.

4] *Refuge management.*

Insecticide treatment for European corn borer (ECB), corn earworm (CEW), southwestern corn borer (SWCB), and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for 1 or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions

to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

*Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Rootworm Refuge for the Cry34/35Ab1 Component

1] *Refuge size.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a rootworm-protected *Bt* hybrid.

2] *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA Insect Protection corn field.

3] *Refuge management options.* The rootworm refuge can be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.

- The in-field rootworm refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
- Seed mixtures of Herculex® XTRA Insect Protection and rootworm refuge corn are not permitted.
- If the rootworm refuge is planted on rotated ground, then Herculex® XTRA Insect Protection corn must also be planted on rotated ground.
- If the rootworm refuge is planted in continuous corn, the Herculex® XTRA Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
- Application of soil insecticide is permitted in the rootworm refuge.
- Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.

- If aerial insecticides are applied to the rootworm refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® XTRA Insect Protection corn.
- Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present or if pesticide without activity against adult corn rootworms is used. Pests on the Herculex® XTRA Insect Protection corn acres can be treated as needed without having to treat the rootworm refuge.
- The rootworm refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for rootworm control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The rootworm refuge and Herculex® XTRA Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn; however, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

Combined Refuge Option

For the combined refuge option (i.e., the lepidopteran refuge combined with the rootworm refuge by planting non-*Bt* corn), the refuge must be planted and managed such that it is consistent with the requirements of the individual traits, Cry1F and Cry34/35Ab1.

1] *Refuge size.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge in corn-growing areas and 50% refuge in cotton-growing areas consisting of non-*Bt* corn. For the latter, see the list of states labeled with “*” in the “Lepidopteran Refuge for the Cry1F Component” section.

2] *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA Insect Protection corn field.

3] *Refuge management options.*

- The in-field combined refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
- Seed mixtures of Herculex® XTRA Insect Protection and combined refuge corn are not permitted.

- If the combined refuge is planted on rotated ground, then Herculex® XTRA Insect Protection corn must also be planted on rotated ground.
- If the combined refuge is planted in continuous corn, the Herculex® XTRA Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
- Application of soil insecticide for corn rootworm control is permitted in the combined refuge.
- Seed treatment is permitted in the combined refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the combined refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® XTRA Insect Protection corn.
- Insecticide treatments in the combined refuge for control of ECB, CEW, SWCB, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one (1) or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). These pests can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.
- Pests other than adult corn rootworms can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Herculex® XTRA Insect Protection corn acres can be treated as needed without having to treat the combined refuge.
- The combined refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for lepidopteran or rootworm control (i.e., herbicide-tolerant corn or conventional corn).
- The combined refuge and Herculex® XTRA Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.

b. Grower Agreements for Herculex® XTRA Insect Protection Corn

1] Persons purchasing Herculex® XTRA Insect Protection corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.

- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] Pioneer must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® XTRA Insect Protection corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] Pioneer must continue to use its current grower agreement for Herculex® XTRA Insect Protection corn. If Pioneer wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5] Pioneer must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® XTRA Insect Protection corn sign grower agreement(s).
- 6] Pioneer shall maintain records of all Herculex® XTRA Insect Protection corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.
- 7] Annually, Pioneer shall provide EPA with a report showing the number of units of Herculex® XTRA Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the 12-month period covering the prior August through July.
- 8] Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

c. IRM Education and Compliance Monitoring Programs for Herculex® XTRA Insect Protection Corn

- 1] Pioneer must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Herculex® XTRA Insect Protection corn users the importance of complying with the IRM program. The program shall include information encouraging Herculex® XTRA Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Herculex® XTRA Insect Protection corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its

records. The program shall involve at least one written communication annually to each Herculex® XTRA Insect Protection corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Pioneer shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Annually, Pioneer must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Pioneer must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4] Pioneer must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Herculex® XTRA Insect Protection corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Pioneer's *Bt* corn products. Pioneer shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5] Pioneer must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Pioneer must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to Pioneer's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6) The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of Herculex® XTRA Insect Protection corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable

sensitivity for comparing results across the United States.

- i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Pioneer shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. Pioneer shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, Pioneer shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Pioneer must confer with EPA prior to adopting any changes.

11] Pioneer shall conduct an annual on-farm assessment program. Pioneer shall train its representatives who make on-farm visits with Herculex® XTRA Insect Protection corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12] Pioneer shall carry out a program for investigating legitimate tips and complaints that Herculex® XTRA Insect Protection corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its phased compliance approach.

13] If a grower, who purchases Herculex® XTRA Insect Protection corn for planting, was specifically identified as not being in compliance during the previous year, Pioneer shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Annually, Pioneer shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Pioneer shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints,

grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Pioneer may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15] Pioneer and the seed corn dealers for Pioneer must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16] Pioneer shall revise and expand its existing compliance assurance program to include the following elements. Pioneer must prepare and submit, on or before January 31, 2011, a written description of its revised compliance assurance program. Pioneer may coordinate with other registrants in designing and implementing its compliance assurance program.

17] Pioneer will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all Herculex® XTRA Insect Protection corn seed bags or bag tags. The Herculex® XTRA Insect Protection corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three (3) growing seasons. Revised Herculex® XTRA Insect Protection corn labels must be submitted by January 31, 2011, 50% implementation on the Herculex® XTRA Insect Protection corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18] Pioneer will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Herculex® XTRA Insect Protection corn is used.

19] Pioneer will use its available Herculex® XTRA Insect Protection corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information

indicates they have purchased Herculex® XTRA Insect Protection corn but may have purchased little or no refuge seed from the registrant, licensees, or affiliated companies.

20] Pioneer will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

21] Annually, Pioneer will refine the on-farm assessment program for Herculex® XTRA Insect Protection corn to reflect the adoption rate and level of refuge compliance for Herculex® XTRA Insect Protection corn.

22] Pioneer will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two (2) years by Pioneer, a seed supplier, or a third party assessor, after completing the assessment process.
- ii. Pioneer will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Herculex® XTRA Insect Protection corn within a 5-year period will be denied access to Pioneer's *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan for Herculex® XTRA Insect Protection Corn

1] EPA is imposing the following conditions for the Cry1F toxin expressed in Herculex® XTRA Insect Protection corn:

Pioneer will monitor for resistance to Cry1F expressed in Herculex® XTRA Insect Protection corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

Focused Population Sampling

Pioneer shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (southwestern corn borer; SWCB), and

Helicoverpa zea (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to Herculex® XTRA Insect Protection corn and/or changes in resistance allele frequency in response to the use of Herculex® XTRA Insect Protection corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of twelve (12) populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six (6) populations. For CEW, the target will be a minimum of ten (10) populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Herculex® XTRA Insect Protection corn. EPA shall be consulted prior to the implementation of such modifications.

Pioneer will report to EPA, on or before August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1F protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before August 31st. The investigative steps will include the following:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Herculex® XTRA Insect Protection corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:

- determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
- estimating the resistance allele frequency in the original population;
- determining whether the resistance allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Pioneer will consult with EPA to develop and implement a case-specific resistance management action plan.

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

Pioneer will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Pioneer will instruct its customers to contact them if such incidents occur. Pioneer will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Pioneer will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected Resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect-feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant

to Herculex® XTRA Insect Protection corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Pioneer will instruct growers to do the following:

- Use alternative control measures in Herculex® XTRA Insect Protection corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Herculex® XTRA Insect Protection corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, Pioneer will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed Resistance

EPA defines ***confirmed resistance*** to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is ***confirmed*** (as defined above), the following steps will be taken by Pioneer:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;
- Pioneer will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Pioneer will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before August 31st of each year, for the duration of the registration.

2] EPA is imposing the following conditions for the Cry34Ab1 and Cry35Ab1 toxins expressed in Herculex® XTRA Insect Protection corn:

- i. Pioneer must monitor for Cry34/35Ab1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- ii. The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.

- iii. Pioneer must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season, with reporting in 2012. As part of this effort, Pioneer must investigate the feasibility of using the Sublethal Seedling Assay¹ as a diagnostic assay. A report of Pioneer's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.
- iv. Pioneer must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to Cry34/35Ab1. As part of the effort, Pioneer may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Pioneer's progress towards this requirement must be submitted within one (1) year from the date of this amended registration.
- v. Pioneer must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry34/35Ab1 within six (6) months from the date of this amended registration.
- vi. Pioneer must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. Pioneer must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.
- viii. The remedial action plan is designed as a tiered approach for mitigating *Diabrotica virgifera virgifera* (western corn rootworm; WCRW), *Diabrotica barberi* (northern corn rootworm; NCRW), and *Diabrotica virgifera zea* (Mexican corn rootworm; MCRW) resistance development to the Cry34Ab1 and Cry35Ab1 proteins. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to the target pests is confirmed.

Definition of Suspected Resistance

Resistance will be *suspected* if investigations of unexpected damage reports show the following:

- i. implicated corn plant roots were expressing the Cry34Ab1 and Cry35Ab1 proteins at the expected levels;

¹ Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188.

- ii. the seed used was not mixed with non-Cry34/35Ab1 seed;
- iii. alternative causes of damage or lodging, such as nontarget pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out; and
- iv. the level of damage exceeds guidelines for expected damage.

If resistance is *suspected*, Pioneer will instruct affected growers to use alternate pest control measures, such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

Confirmation of Resistance

Resistance will be *confirmed* if all of the following criteria are met by progeny from the target pest species sampled from the area of *suspected resistance*:

- i. the proportion of larvae that can feed and survive on Herculex® XTRA Insect Protection corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
- ii. the LC₅₀ of the test population exceeds the upper limit of the 95% confidence interval for the LC₅₀ of a standard unselected population, and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
- iii. the ability to survive is heritable;
- iv. Herculex® XTRA Insect Protection corn plant assays determine that damage caused by surviving insects would exceed economic thresholds; and
- v. if subsequent collections in the affected field area demonstrate similar bioassay results.

Response to Confirmed Resistance

When resistance is *confirmed*, the following steps will be taken:

- i. EPA will receive notification within 30 days of confirming resistance;
- ii. affected customers and extension agents will be notified about confirmed resistance;
- iii. affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures;

- iv. sale and distribution of Herculex® XTRA Insect Protection corn in the affected area will cease immediately; and
- v. a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs.

e. Annual Reporting Requirements for Herculex® XTRA Insect Protection Corn

- 1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2) Grower Agreement Results: number of units of Herculex® XTRA Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3) Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.
- 4) Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5) Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer/Dupont	29964-8	TC1507 (PO Cry1F) x DAS-59122 (Cry34Ab1/Cry35Ab1) x MON810 (Cry1Ab)	24 February 2010	Conditional	31 October 2010

Pioneer Hi-Bred International Corn PIP Products

Three Pioneer Hi-Bred International corn PIP products (1507 X MON810, EPA Reg No. 29964-7; 1507 X 59122 X MON810, EPA Reg. No 29964-8; and 59122 X MON810, EPA Reg. No. 29964-9) were registered February 24, 2010 with an expiration date of October 31, 2010. As part of the Agency's public participation initiative, the Agency provided for a concurrent public comment period which closed March 28, 2010. During this comment period, the Agency received several comments on these products. These comments and comments pertinent to these registrations submitted as part of the 2010 Bt Corn Reassessment comment period will be addressed separately, by the October 31, 2010 expiration date.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer/Dupont	29964-9	DAS-59122 (PO Cry34Ab1/Cry35Ab1) x MON810 (Cry1Ab)	24 February 2010	Conditional	31 October 2010

Pioneer Hi-Bred International Corn PIP Products

Three Pioneer Hi-Bred International corn PIP products (1507 X MON810, EPA Reg No. 29964-7; 1507 X 59122 X MON810, EPA Reg. No 29964-8; and 59122 X MON810, EPA Reg. No. 29964-9) were registered February 24, 2010 with an expiration date of October 31, 2010. As part of the Agency's public participation initiative, the Agency provided for a concurrent public comment period which closed March 28, 2010. During this comment period, the Agency received several comments on these products. These comments and comments pertinent to these registrations submitted as part of the 2010 Bt Corn Reassessment comment period will be addressed separately, by the October 31, 2010 expiration date.

IV. mCry3A BRAD Registered Products

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Syngenta	67979-5	<i>Bt</i> Corn Event MIR 604 with modified Cry3A (Agrisure RW)	3 October 2006	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Agrisure® RW (MIR604) Rootworm-Protected (MIR604) Corn with modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn SYN-IR604-5.
- 3] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4] Three (3) year full-scale field or semi-field studies for evaluation of mCry3A Event MIR604 corn exposure on non-target invertebrates must be conducted. Full-scale field experiments must be appropriately designed to provide a measure of ecological impacts (larger fields, more replicates, more samples per plot based on recommendations of the August, 2002 SAP and subsequent relevant research on appropriate study design). A protocol is due within 90 days of the date of registration. A final report is due January 31, 2011.

- 5] The subject plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 6] You must commit to do the following Insect Resistance Management Program:

a. **Refuge Requirements.**

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

- 1) Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.
- 2) Specifically, growers must plant a structured refuge of at least 20% non-corn rootworm protected *Bt* corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworms are present unless the Agrisure® RW (MIR604) Rootworm-Protected Corn field is treated in a similar manner.
- 3) Refuge planting options include: refuge acres should be planted as blocks adjacent to Agrisure® RW (MIR604) Rootworm-Protected Corn Rootworm-Protected Corn fields, perimeter strips, or as in-field strips.
- 4) External refuges must be planted adjacent to (e.g., across the road from) Agrisure® RW (MIR604) Rootworm-Protected Corn fields.
- 5) When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.
- 6) Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Agrisure® RW (MIR604) Rootworm-Protected Corn field is treated in a similar manner.
- 7) If the refuge is planted in a field that is in a crop rotation system, then Agrisure® RW (MIR604) Rootworm-Protected Corn must also be planted in a field that is in a crop

rotation system.

- 8) If the refuge is planted on continuous corn, then the Agrisure® RW (MIR604) Rootworm-Protected Corn field may be planted on either continuous or in a field that is in a crop rotation system.

b. Grower Agreements

- 1) Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Agrisure® RW (MIR604) Rootworm-Protected Corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Syngenta must continue to use its current grower agreement for Agrisure® RW (MIR604) Rootworm-Protected Corn product. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5) Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Agrisure® RW (MIR604) Rootworm-Protected Corn product sign grower agreement(s).
- 6) Syngenta shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Annually Syngenta shall provide EPA with a report showing the number of units of its *Bt* Agrisure® RW (MIR604) Rootworm-Protected Corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8) Annually Syngenta shall submit annual reports on units sold by State (units sold by county level will be made available to the Agency upon request), IRM grower

agreement results, and the compliance assurance program, including the education program on or before January 31st each year.

- 9) Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

- 1) Syngenta must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Agrisure® RW (MIR604) Rootworm-Protected Corn product users the importance of complying with the IRM program. The program shall include information encouraging Agrisure® RW (MIR604) Rootworm-Protected Corn product users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Agrisure® RW (MIR604) Rootworm-Protected Corn product fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Agrisure® RW (MIR604) Rootworm-Protected Corn product user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.
- 2) Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Annually, Syngenta must provide a report to EPA summarizing the activities carried out under the education program for the prior year and any substantive changes to its grower education activities as part of the overall IRM Compliance Assurance Program (CAP) report. The required features of the Compliance Assurance Program are described in paragraphs 4 to 22 below.
- 4) Syngenta must continue to implement and improve an ongoing IRM Compliance Assurance Program designed to evaluate the extent to which growers purchasing Agrisure® RW (MIR604) Rootworm-Protected Corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta corn PIP products. Syngenta shall coordinate with other *Bt* corn registrants in improving its Compliance Assurance Program and continue to integrate this amended registration into the current Compliance Assurance Program used for its other *Bt* corn plant-incorporated protectants. Other required features of

the program are described in paragraphs 5–22.

- 5) Syngenta must maintain and publicize a “phased compliance approach,” i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance 2 years in a row would be denied access to the registrant’s *Bt* corn products the next year. Additionally, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.
- 6) The IRM Compliance Assurance Program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.
 - (a) A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
- 7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9) Syngenta shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31.
- 10) Annually, Syngenta shall revise, and expand as necessary, its Compliance Assurance Program to take into account the information collected through the compliance survey required under paragraphs 6 through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes to a previously approved CAP.

- 11) Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with growers of their *Bt* corn products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12) Syngenta shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach."
- 13) If a grower, who purchases Agrisure® RW (MIR604) Rootworm-Protected *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- 14) Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings.
- 15) Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.
- 16) Syngenta shall revise and expand its existing Compliance Assurance Program to include the following elements. Syngenta must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. Syngenta may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
- 17) Syngenta will enhance the refuge education program throughout the seed delivery channel to:

- (a) Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
 - (b) Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011; 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season; and full implementation must occur by the 2013 growing season.
- 18) Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance and will:
- (a) Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
 - (b) Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.
- 19) Syngenta will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of grower compliance with refuge requirements:
- (a) Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from Syngenta, licensee, or affiliated company.
- 20) Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:
- (a) The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.
- 21) Syngenta will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.
- 22) Syngenta will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:
- (a) All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.
 - (b) Syngenta will conduct follow-up checks on growers found to be significantly out

of compliance within 3 years after they are found to be back in compliance.

- (c) A grower found with a second incident of significant non-compliance with refuge requirements for Agrisure® RW (MIR604) Rootworm-Protected Corn product within a 5-year period will be denied access to and/or sales of the registrant's Bt corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan

The Agency is imposing the following conditions for the mCry3A toxin expressed in this product:

- 1) Syngenta must monitor for mCry3A resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- 2) The resistance monitoring plan must include: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life-stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and an interim description of rootworm damage guidelines.
- 3) Syngenta must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season with reporting in 2012. As part of this effort, Syngenta must investigate the feasibility of using the Sublethal Seedling Assay (Nowatzki et al. 2008)^{IV} as a diagnostic assay. A report on Syngenta's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.
- 3) Syngenta must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to mCry3A toxin. As part of the effort, Syngenta may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Syngenta's progress towards this requirement must be submitted within one year (12 months) from the date of this amended registration.
- 4) Syngenta must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage). The revised guidelines must take into consideration the comments and recommendations from EPA's June 30, 2010, review of the rootworm resistance monitoring program for mCry3A. A report on this requirement must be

^{IV} Reference: Nowatzki, T., S.A. Lefko, R.R. Binning, S.D. Thompson, T.A. Spencer, B.D. Siegfried, 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132: 177-188.

submitted to the Agency within six (6) months from the date of the amended registration.

- 5) Syngenta must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- 6) Syngenta must provide EPA with an annual resistance monitoring report by August 31st of each year, reporting on populations collected the previous year.

e. **Remedial Action Plans**

The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed (this general process has been implemented for CRW *Bt* corn products).

- 1) **Definition of Suspected Resistance:** Resistance will be suspected if investigations of unexpected damage reports show that:
 - (a) implicated maize plant roots were expressing the mCry3A protein at the expected level;
 - (b) alternative causes of damage or lodging, such as non-target pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out;
 - (c) the level of damage exceeds guidelines for expected damage.
- 2) If resistance is “suspected”, Syngenta will instruct affected growers to use alternate pest control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year’s pest population.
- 3) **Confirmation of Resistance:** Resistance will be confirmed if all of the following criteria are met by progeny from the target pest species sampled from the area of “suspected resistance.”
 - (a) the proportion of larvae that can feed and survive on mCry3A roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
 - (b) the LC₅₀ of the test population exceeds the upper limit of the 95% confidence interval for the LC₅₀ of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
 - (c) the ability to survive is heritable;

- (d) mCry3A plant assays determine that damage caused by surviving insects would exceed economic thresholds;
 - (e) the identified frequency of field resistance could lead to widespread product failure if subsequent collections in the affected field area(s) demonstrated similar bioassay results.
- 4) **Response to Confirmed Resistance:** When resistance is “confirmed”, the following steps will be taken:
- (a) EPA will receive notification within 30 days of resistance confirmation;
 - (b) affected customers and extension agents will be notified about confirmed resistance;
 - (c) affected customers and extension agents will be encouraged to employ alternative CRW control measures;
 - (d) sale and distribution of mCry3A maize in the affected area will cease immediately;
 - (e) a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs. The details of such a plan should be approved by EPA and all appropriate stakeholders.

f. **Annual Reporting Requirements**

- 1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- 2) Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year;
- 4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5) Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Syngenta	67979-8	<i>Bt</i> Corn Event MIR 604 + <i>Bt</i> 11 with modified Cry3A + Cry1Ab (Agrisure CB/RW)	24 January 2007	Conditional (amended 29 September 2010)	30 September 2015

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to mCry3A (MIR604) corn with modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn SYN-IR604-5. and *Bacillus thuringiensis* Cry1Ab delta-endotoxin protein (*Bt*11) and the genetic material necessary for its product (via elements of vector pZ01502 in corn (SYN-BT011-1)
- 3] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4] The subject plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5] Three (3) year full-scale field or semi-field studies for evaluation of mCry3A Event MIR604 corn exposure on non-target invertebrates must be conducted. Full-scale field experiments must be appropriately designed to provide a measure of ecological impacts (larger fields, more replicates, more samples per plot based on recommendations of the August, 2002 SAP and subsequent relevant research on appropriate study design). A protocol is due within 90 days of the date of registration. A final report is due January 31, 2011.
- 6] Submit/cite all data, determined by the Agency to be acceptable, required to support the individual plant-incorporated protectants in Event MIR 604 with modified Cry3A (Agrisure RW) corn and *Bacillus thuringiensis* corn Event *Bt*11 with Cry 1Ab for use in field corn within the timeframes required by the terms and conditions of EPA Registration Numbers 67979-5 and 67979-1.
- 7] You must commit to do the following Insect Resistance Management Program:

a. Refuge Requirements

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

Corn Belt/Non-Cotton-Growing Area Refuge Requirements

For Bt11 x MIR604 Field Corn (expressing Cry1Ab and mCry3A proteins) grown in non-cotton-growing areas of the United States, two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x MIR604 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 x MIR604 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR604 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x MIR604 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 x MIR604 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

Growers who fail to comply with the IRM requirements risk losing access to Syngenta corn PIP products.

Corn/Cotton-Growing Area (Cotton-Growing Area) Refuge Requirements

For Bt11 x MIR604 grown in cotton-growing areas of the United States, the common refuge and separate refuge options are also available; however, the refuge area is larger. Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x MIR604 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 x MIR604 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR604 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x MIR604 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 x MIR604 field must be treated in a similar manner. Economic

thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

Growers who fail to comply with the IRM requirements risk losing access to Syngenta corn PIP products.

b. Grower Agreements

- 1) Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x MIR604 corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Syngenta must continue to use its current grower agreement for Bt11 x MIR604 corn product. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5) Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x MIR604 corn product sign grower agreement(s).
- 6) Syngenta shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Annually, Syngenta shall provide EPA with a report showing the number of units of its Bt11 x MIR604 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8) Annually, Syngenta shall submit annual reports on units sold by State (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program, including the education program on or before January 31st each year.

- 9) Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

- 1) Syngenta must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Bt11 x MIR604 corn product users the importance of complying with the IRM program. The program shall include information encouraging Bt11 x MIR604 corn product users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 x MIR604 corn product fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt11 x MIR604 corn product user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.
- 2) Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Annually, Syngenta must provide a report to EPA summarizing the activities carried out under the education program for the prior year and any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs 4-22 below.
- 4) Syngenta must continue to implement and improve an ongoing IRM Compliance Assurance Program (CAP) designed to evaluate the extent to which growers purchasing Bt11 x MIR604 corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta corn PIP products. Syngenta shall coordinate with other *Bt* corn registrants in improving its Compliance Assurance Program and continue to integrate this amended registration into the current Compliance Assurance Program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5-22.
- 5) Syngenta must maintain and publicize a “phased compliance approach,” i.e., a

guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance 2 years in a row would be denied access to the registrant's *Bt* corn products the next year. Additionally, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

- 6) The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.
 - a. A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
- 7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9) Syngenta shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. Syngenta shall confer with other *Bt* corn registrants and EPA on the design and content of the survey prior to its implementation.
- 10) Annually, Syngenta shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6 through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes to a previously approved CAP.
- 11) Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train

- its representatives who make on-farm visits with growers of their *Bt* corn products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12) Syngenta shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach."
 - 13) If a grower who purchases Bt11 x MIR604 corn for planting was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
 - 14) Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase Bt corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings.
 - 15) Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.
 - 16) Syngenta shall revise and expand its existing Compliance Assurance Program to include the following elements. Syngenta must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. Syngenta may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
 - 17) Syngenta will enhance the refuge education program throughout the seed delivery channel to:
 - a. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences

of failure to plant the required refuge;

- b. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011; 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season; and full implementation must occur by the 2013 growing season.

18) Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance and will:

- a. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- b. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19) Syngenta will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- a. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from Syngenta, licensee, or affiliated company.

20) Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- a. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.

21) Syngenta will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

22) Syngenta will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- a. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.
- b. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within 3 years after they are found to be back in

compliance.

- c. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 x MIR604 corn product within a 5-year period will be denied access to and/or sales of the registrant's *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan (mCry3A – Corn Rootworm)

The Agency is imposing the following conditions for the mCry3A toxin expressed in this product:

- 1) Syngenta must monitor for mCry3A resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- 2) The resistance monitoring plan must include: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life-stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and an interim description of rootworm damage guidelines.
- 3) Syngenta must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season with reporting in 2012. As part of this effort, Syngenta must investigate the feasibility of using the Sublethal Seedling Assay (Nowatzki et al. 2008)^V as a diagnostic assay. A report on Syngenta's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.
- 7) Syngenta must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to mCry3A toxin. As part of the effort, Syngenta may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Syngenta's progress towards this requirement must be submitted within one year (12 months) from the date of this amended registration.
- 8) Syngenta must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage). The revised guidelines must take into consideration the

^V Reference: Nowatzki, T., S.A. Lefko, R.R. Binning, S.D. Thompson, T.A. Spencer, B.D. Siegfried, 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132: 177-188.

comments and recommendations from EPA's June 30, 2010, review of the rootworm resistance monitoring program for mCry3A. A report on this requirement must be submitted to the Agency within six (6) months from the date of the amended registration.

- 9) Syngenta must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- 10) Syngenta must provide EPA with an annual resistance monitoring report by August 31st of each year, reporting on populations collected the previous year.

e. Remedial Action Plans

The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed (this general process has been implemented for other lepidopteron and CRW *Bt* corn products).

- 1) Definition of Suspected Resistance: Resistance will be suspected if investigations of unexpected damage reports show that:
 - a. implicated maize plant roots were expressing the mCry3A protein at the expected level;
 - b. alternative causes of damage or lodging, such as non-target pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out;
 - c. the level of damage exceeds guidelines for expected damage.
- 2) If resistance is "suspected", Syngenta will instruct affected growers to use alternate pest control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.
- 3) Confirmation of Resistance: Resistance will be confirmed if all of the following criteria are met by progeny from the target pest species sampled from the area of "suspected resistance:"
 - a. the proportion of larvae that can feed and survive on mCry3A roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
 - b. the LC_{50} of the test population exceeds the upper limit of the 95% confidence interval for the LC_{50} of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;

- c. the ability to survive is heritable;
 - d. mCry3A plant assays determine that damage caused by surviving insects would exceed economic thresholds;
 - e. the identified frequency of field resistance could lead to widespread product failure if subsequent collections in the affected field area(s) demonstrated similar bioassay results.
- 4) Response to Confirmed Resistance: When resistance is “confirmed”, the following steps will be taken:
- a. EPA will receive notification within 30 days of resistance confirmation;
 - b. affected customers and extension agents will be notified about confirmed resistance;
 - c. affected customers and extension agents will be encouraged to employ alternative CRW control measures;
 - d. sale and distribution of mCry3A maize in the affected area will cease immediately;
 - e. a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs. The details of such a plan should be approved by EPA and all appropriate stakeholders.

f. Insect Resistance Monitoring (Cry1Ab – Corn Borer)

The Agency is imposing the following conditions for this product:

Syngenta will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

1) Focused Population Sampling

Syngenta shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; S WCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes

in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

- a. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
- b. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
- c. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
 - (a) determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);

- (b) estimating the resistance-allele frequency in the original population;
- (c) determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- (d) determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with the Agency to develop and implement a case-specific resistance management action plan.

2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Syngenta will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- (a) the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- (b) the seed used had the proper percentage of corn expressing *Bt* protein;
- (c) the relevant plant tissues are expressing the expected level of *Bt* protein; and
- (d) it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Syngenta will instruct growers to do the following:

- (a) Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- (b) Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- (a) There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
 - (b) In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
 - (c) In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.
- 3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Syngenta:

- (a) EPA will receive notification within 30 days of resistance confirmation;
- (b) Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- (c) Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- (d) If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- (e) Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- (f) Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- (g) Syngenta will notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- (h) In subsequent growing seasons, Syngenta will maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of Cry1Ab corn constitutes acceptance of these conditions.

g. Annual Reporting Requirements

- 1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- 2) Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year;

- 4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5) Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

V. MON89034 BRAD Registered Products

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Monsanto	524-575	<i>Bt</i> corn Event MON 89034 with Cry1A.105 + CryAb2	10 June 2008	Conditional (amended 29 September 2010)	30 September 2022

- 1) The subject registration will automatically expire on midnight September 30, 2022.
- 2) The subject registration will be limited to MON 89034 [*Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production (vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3) for use in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn must not be sold to small roadside or home growers.
- 3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4) This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management – Resistance Monitoring	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against Southwestern corn borer (SWCB), and for the Cry2Ab2 protein against SWCB. These data were submitted and are being evaluated.	
Insect Resistance Management – Resistance Monitoring	To support sweet corn uses, baseline susceptibility studies must be conducted on fall armyworm (FAW) populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 5,000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2012*

* Extensions were granted as listed in the above table.

- 6) You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
- Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 field corn.
 - Requirements for Monsanto Company (Monsanto) to prepare and require MON 89034 users to sign “grower agreements,” that impose binding contractual obligations on the grower to comply with the refuge requirements.
 - Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
 - Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers’ compliance with IRM requirements.
 - Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1A.105 and Cry2Ab2 proteins in the target insects.
 - Requirements for Monsanto to develop, and if triggered, to implement a “remedial action plan,” that contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;
 - Requirements for Monsanto, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program.
 - Requirements for Monsanto, on or before August 31st of each year, to submit reports on resistance monitoring.

a) Refuge Requirements for MON 89034 Field Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Monsanto to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

1) Corn-Belt Refuge Requirements

For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 5% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.
- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within ½ mile.

- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.
- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

b) Post-Harvest Requirements for MON 89034 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
- The allowed crop destruction methods are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving resistant insects.

c) Grower Agreements for MON 89034

- 1) Persons purchasing MON 89034 must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the

grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

- 3) Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 89034 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Monsanto must continue to use its current grower agreement for MON 89034 corn. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5) Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 89034 corn sign grower agreement(s).
- 6) Monsanto shall maintain records of all MON 89034 grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Annually, Monsanto shall provide EPA with a report showing the number of units of MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

d) IRM Education and Compliance Monitoring Programs for MON 89034

- 1) Monsanto must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to MON 89034 corn users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 89034 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its

education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

- 2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraphs 6a or 6b and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Annually Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.
- 4) Monsanto must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Monsanto corn PIP products. Monsanto shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.
- 5) Monsanto must maintain and publicize a “phased compliance approach,” i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to Monsanto’s *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn
- 6a) MON 89034 Field Corn: The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 89034 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical

resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

- i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
- 6b) MON 89034 Sweet Corn: The IRM compliance assurance program shall include an annual survey of all MON 89034 sweet corn customers who purchase 5 or more bags of MON 89034 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.
- 7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9a) MON 89034 Field Corn: Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.
- 9b) MON 89034 Sweet Corn: Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA on or before January 31st of each year. Monsanto shall confer with EPA on changes to the design and content of the survey prior to its implementation.
- 10) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6a through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with the Agency prior to adopting any changes.
- 11) Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of MON 89034 to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action,

consistent with its “phased compliance approach,” to promote compliance.

- 12) Monsanto shall carry out a program for investigating legitimate “tips and complaints” that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its “phased compliance approach.”
- 13) If a grower, who purchases MON 89034 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.
- 14) Annually, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, Monsanto shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase Bt corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.
- 15) Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.
- 16) Monsanto shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
- 17) The registrant will enhance the refuge education program throughout the seed delivery channel:
 - i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
 - ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing

season, and full implementation must occur by the 2013 growing season.

18) Monsanto will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

19) Monsanto will use its available MON 89034 sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the MON 89034 corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

20) Monsanto will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment

21) Annually, Monsanto will refine the on-farm assessment program for the MON 89034 corn product to reflect the adoption rate and level of refuge compliance for MON 89034 .

22) Monsanto will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by Monsanto, a seed supplier, or third party assessor, after completing the assessment process;
- ii. Monsanto will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for MON 89034 corn within a five-year period will be denied access to and/or sales of Monsanto's *Bt* corn products the next year.

e) Insect Resistance Monitoring and Remedial Action Plan for MON 89034

- 1) The Agency is imposing the following conditions for the Cry1A.105 and Cry2Ab2 toxins expressed in MON 89034:

- i. Monsanto must monitor for resistance to Cry1A.105 and Cry2Ab2 expressed in MON 89034.
- ii. The resistance monitoring program must include the following two approaches: (1) focused population sampling and laboratory testing and (2) investigation of reports of less-than expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

Monsanto must develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Monsanto should consult with academic and United States Department of Agriculture (USDA) experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31st of the year following that in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Annually, Monsanto shall sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 and/or changes in resistance-allele frequency in response to the use of MON 89034 and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034. The Agency shall be consulted prior to the implementation of such modifications.

Monsanto will report to the Agency by August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105 and Cry2Ab2 proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding.

Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to taken to evaluate the resistance. These steps may include:
 - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
 - estimating the resistance-allele frequency in the original population;
 - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, CEW, and FAW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 89034 fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the

affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

f) Annual Reporting Requirements for MON 89034

- 1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2) Grower Agreement Results: number of units of MON 89034 seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3) Grower Education: substantive changes to education program completed previous year, on or before January 31st of each year,.
- 4) Compliance Assurance Plan: Compliance Assurance Program activities and results, for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5) Compliance Assurance Plan Survey Results: to include annual survey results and plans for the next year; on or before January 31st of each year.
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st each year.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Monsanto	524-576	<i>Bt</i> corn Event MON 89034 + MON 88017 with Cry1A.105 + Cry2Ab2 + Cry3Bb1	10 June 2008	Conditional (amended 29 September 2010)	30 September 2015

- 1) The subject registration will automatically expire on midnight September 30, 2015.
- 2) The subject registration will be limited to MON 89034 x MON 88017 [*Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production (vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3) x *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)] for use in field or sweet corn. Further, MON 89034 x MON 88017 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 x MON 88017 sweet corn must not be sold to small roadside or home growers.
- 3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4) This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management – Resistance Monitoring	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against Southwestern corn borer (SWCB), and for the Cry2Ab2 protein against SWCB. These data were submitted and are being evaluated.	
Insect Resistance Management – Resistance Monitoring	To support sweet corn uses, baseline susceptibility studies must be conducted on fall armyworm (FAW) populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas	4/1/2012

	in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 5,000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	
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* Extensions were granted as listed in the above table.

6) You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:

- Requirements relating to creation of a refuge for the Cry3Bb1, Cry1A.105, and Cry2Ab2 components that meets the requirements of the individual traits. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1A.105 and Cry2Ab2 components, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry3Bb1 component.
- Requirements for Monsanto Company (Monsanto) to prepare and require MON 89034 x MON 88017 users to sign “grower agreements,” that impose binding contractual obligations on the grower to comply with the refuge requirements.
- Requirements for Monsanto to develop, implement and report to EPA on programs to educate growers about IRM requirements.
- Requirements for Monsanto to develop, implement and report to EPA on programs to evaluate and promote growers’ compliance with IRM requirements.
- Requirements for Monsanto to develop, implement and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins in the target insects.
- Requirements for Monsanto to develop, and if triggered to implement a “remedial action plan,” that contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA.
- Requirements for Monsanto, on or before January 31st of each year, to submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program on or before January 31st each year.
- Requirements for Monsanto, on or before August 31st of each year, to submit reports on resistance monitoring.

a) Refuge Requirements for MON 89034 x MON 88017 Field Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by the registrant to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

1) Corn-Belt Refuge Requirements

For MON 89034 x MON 88017 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide. Two options for the deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and refuge acres). It must be planted as a block adjacent to the MON 89034 x MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals); however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-*Bt*/lepidopteran-protected hybrid, must represent at least 5% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 89034 x MON 88017 field. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge may be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control or a non-*Bt* foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals). The corn rootworm refuge must be planted with a non-*Bt*/corn rootworm-protected hybrid but may be planted with *Bt* corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field

strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 field must be treated in a similar manner.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 x MON 88017 field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Two options for the deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and refuge acres). It must be planted as a block adjacent to the MON 89034 x MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals); however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-*Bt*/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 89034 x MON 88017 field.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge may be treated with a

soil- applied or seed-applied insecticide for corn rootworm larval control or a non-*Bt* foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals). The corn rootworm refuge must be planted with a non-*Bt*/corn rootworm-protected hybrid but may be planted with *Bt* corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field must be treated in a similar manner.

b) Post-Harvest Requirements for MON 89034 x MON 88017 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
- The allowed crop destruction methods are: rotary mowing, disking, or plow down. Crop destruction methods should destroy any surviving resistant insects.

c) Grower Agreements for MON 89034 x MON 88017

- 1) Persons purchasing MON 89034 x MON 88017 must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 89034 x MON 88017 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Monsanto must continue to use its current grower agreement for MON 89034 x MON 88017 corn. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5) Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 89034 x MON 88017 corn sign grower agreement(s).
- 6) Monsanto shall maintain records of all MON 89034 x MON 88017 grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

- 7) Annually, Monsanto shall provide EPA with a report showing the number of units of MON 89034 x MON 88017 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July
- 8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

d) IRM Education and Compliance Monitoring Programs for MON 89034 x MON 88017

- 1) Monsanto must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to MON 89034 x MON 88017 corn users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 x MON 88017 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 x MON 88017 corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 89034 x MON 88017 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.
- 2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraphs 6a -8 of this section and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Annually, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).
- 4) Monsanto must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing [MON 89034 x MON 88017 corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Monsanto's corn PIP products. Monsanto shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current

compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.

- 5) Monsanto. must maintain and publicize a “phased compliance approach,” i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access to Monsanto’s *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.
- 6a) MON 89034 x MON 88017 Field Corn: The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 89034 x MON 88017 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.
 - i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
- 6b) MON 89034 x MON 88017 Sweet Corn: The IRM compliance assurance program shall include an annual survey of all MON 89034 x MON 88017 sweet corn customers who purchase 5 or more bags of MON 89034 x MON 88017 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 x MON 88017 sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.
- 7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

- 9a) MON 89034 x MON 88017 Field Corn: Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year, beginning in 2010. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.
- 9b) MON 89034 x MON 88017 Sweet Corn: Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA on or before January 31st of each year, beginning in 2010. Monsanto shall confer with EPA on changes to the design and content of the survey prior to its implementation.
- 10) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6a through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with the Agency prior to adopting any changes.
- 11) Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of MON89034 x MON 88017 to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12) Monsanto shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."
- 13) If a grower, who purchases MON 89034 x MON 88017 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.
- 14) Annually, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, Monsanto shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, Corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase Bt corn seed on the basis of continued non-compliance with the

insect resistance management refuge requirements Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

- 15) Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.
- 16) Monsanto shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
- 17) The registrant will enhance the refuge education program throughout the seed delivery channel:
 - i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
 - ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.
- 18) Monsanto will focus the majority of on-farm assessments on regions with the greatest risks for resistance:
 - i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
 - ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.
- 19) Monsanto will use its available MON 89034 x MON 88017 sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:
 - i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the MON 89034 x MON 88017 corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.
- 20) The registrant will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment
- 21) The registrant will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.
- 22) Monsanto will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:
 - i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by Monsanto, a seed supplier, or third party assessor, after completing the assessment process;
 - ii. Monsanto will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
 - iii. A grower found with a second incident of significant non-compliance with refuge requirements for MON 89034 x 88017 corn within a five-year period will be denied access to and/or sales of Monsanto's Bt corn products the next year.

e) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x MON 88017

- 1) The Agency is imposing the following conditions for the Cry1A.105 and Cry2Ab2 toxins expressed in MON 89034:
 - i. Monsanto must monitor for resistance to Cry1A.105 and Cry2Ab2 expressed in MON 89034.
 - ii. The resistance monitoring program must include the following two approaches: (1) focused population sampling and laboratory testing and (2) investigation of reports of less-than expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(a) Focused Population Sampling

Monsanto must develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Monsanto should consult with academic and United States Department of Agriculture (USDA) experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31st of the year following that in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any

county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Annually, Monsanto shall sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 x MON 88017 and/or changes in resistance-allele frequency in response to the use of MON 89034 x MON 88017 and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034 x MON 88017. The Agency shall be consulted prior to the implementation of such modifications.

Monsanto will report to the Agency by August 31st of each year, beginning in 2010, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105 and Cry2Ab2 proteins in bioassay shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the

diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 x MON 88017 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
 - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
 - estimating the resistance-allele frequency in the original population;
 - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(b) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, CEW, and FAW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be

responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 x MON 88017 in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 89034 x MON 88017 fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 x MON 88017 crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only) .
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(c) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

(2) The Agency is imposing the following conditions for the Cry3Bb1 toxin expressed in MON 88017:

- i. Monsanto must monitor for Cry3Bb1 resistance and/or trends in increased tolerance for corn rootworm utilizing the current corn rootworm resistance monitoring plan for MON 89034 x MON 88017. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- ii. The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.
- iii. Monsanto must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season, with reporting in 2012. As part of this effort, Monsanto must investigate the feasibility of using the Sublethal Seedling Assay^{VI} as a diagnostic assay. A report of Monsanto's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.
- iv. Monsanto must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to Cry3Bb1. As part of the effort, Monsanto may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Monsanto's progress towards this requirement must be submitted within one (1) year from the date of this amended registration.
- v. Monsanto must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry3Bb1 within six (6) months from the date of this amended registration.
- vi. Monsanto must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. Monsanto must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.
- viii. The current remedial action plan approved for Cry3Bb1 must be used for corn rootworm suspected and confirmed resistance in MON 88017 x MON 810. If corn rootworm resistance is confirmed, all acres of MON 88017 x MON 810 and refuges must be treated with insecticides targeted at corn rootworm adults and larvae.

^{VI} Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188.

f) Annual Reporting Requirements for Mon 89034 x MON 88017

- 1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2) Grower Agreement Results: number of units of MON 89034 x MON 88017 seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3) Grower Education: substantive changes to education program completed previous year, on or before January 31st of each year.
- 4) Compliance Assurance Plan: Compliance Assurance Program activities and results, for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
- 5) Compliance Survey Results: to include annual survey results and plans for the next year; full report on or before January 31st of each year.
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st each year.

VI. OAM BRAD Registered Products

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer/Dupont	29964-6	Optimum AcreMax 1 (OAM 1) Seed Blend of Herculex Xtra + Herculex I	30 April 2010	Conditional (amended 29 September 2010)	30 September 2012

- 1] The subject registration will automatically expire on midnight September 30, 2012.
- 2] The subject registration will be limited to a seed mix of DAS-Ø15Ø7-1 (Cry1F) x DAS-59122-7 (Cry34Ab1/Cry35Ab1) corn seed blended with not less than 10% DAS-Ø15Ø7-1 (Cry1F) corn seed.
- 3] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 5] Submit the following data in the timeframes listed:

Study Type	Required Data	Due Date
Insect Resistance Management	Pioneer must provide the Agency with a copy of the grower agreement, associated stewardship documents, and written description of a system, which assures that growers will sign grower agreements and persons purchasing OAM1 corn will annually affirm that they are contractually bound to comply with requirements of the insect resistance management (IRM) program. (This information has been submitted and is being evaluated by the Agency.)	90 days from the date of registration
Insect Resistance Management	Pioneer must implement an enhanced resistance monitoring plan for OAM1. Pioneer must provide the Agency with a baseline (benchmark) study that shows the susceptibility of western corn rootworm populations (WCRW) in the Sublethal Seedling Assay prior to the large-scale introduction of OAM1. Although northern corn rootworm (NCRW) is difficult to rear, Pioneer must attempt to obtain benchmark susceptibility data using the Sublethal Seedling Assay for NCRW as well.	12/1/2010 for WCRW 12/1/11 for NCRW
Insect Resistance	Pioneer must submit a detailed OAM1-specific resistance	12/1/2010

Management	monitoring and remedial action plan, including an analysis to determine the expected field performance criteria for OAM1 products so that unexpected damage can be benchmarked. Pioneer will update the plan by 12/1/2012, if needed, based on continued field evaluation of OAM1 performance.	
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6] Pioneer must implement the following Insect Resistance Management Program:

The required IRM program for OAM1 corn must have the following elements:

Requirements relating to creation of a lepidopteran refuge (consisting of corn that does not contain any *Bt* trait for lepidopteran control) in conjunction with the planting of any acreage of OAM1 corn;

Requirements for Pioneer to prepare and require OAM1 users to sign “grower agreements,” that impose binding contractual obligation on the grower to comply with the refuge requirements;

Requirements regarding programs to educate growers about IRM requirements;

Requirements regarding programs to evaluate and promote growers’ compliance with IRM requirements;

Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F and Cry34Ab1/Cry35Ab1 proteins in the target insects;

Requirements regarding a “remedial action plan,” that contains measures Pioneer would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the educational program on or before January 31st of each year, beginning in 2011.

a) Refuge requirements for OAM1

Because the refuge for corn rootworm is blended in each bag or box of OAM1 seed, no additional corn rootworm refuge is required. A refuge must be planted for corn borers. The refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn borers. Refuge options are based on the planting of OAM1 in cotton or non-cotton growing regions and insect pressure present in those locations. The refuge sizes for these regions are either 50% in cotton-growing regions (*i.e.*, 50 acres of corn that does not contain *Bt* technology for the control of corn borers for every 50 acres of OAM1) or 20% in non-cotton growing regions (*i.e.*, 20 acres of corn that does not contain *Bt* technology for the control of corn borers for every 80 acres of OAM1). Refuge planting options include: separate fields, blocks within fields (*e.g.*, along the edges or headlands), and strips across the field. Cotton-growing regions

consist of the following states Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma(only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott and Stoddard.

External refuges must be planted within ½ mile. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-*Bt* insecticides if the population of one or more of the target lepidopteran pests of OAM1 in the refuge exceeds economic thresholds. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by the registrant to help these growers meet the refuge requirements across their farming operations.

b) Grower Agreement for OAM1 Corn

1. Persons purchasing OAM1 corn must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
2. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
3. Pioneer must implement a system equivalent to what is already approved for previously registered Pioneer *Bt* corn products, which is reasonably likely to assure that persons purchasing OAM1 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration. (This information has been submitted and is being evaluated by the Agency.)
4. Pioneer must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. (This information has been submitted and is being evaluated by the Agency.) If Pioneer wishes to

change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, 30 days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure it is consistent with the terms and conditions of this registration.

5. Pioneer shall maintain records of all OAM1 corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
6. Beginning on January 31, 2011, and annually thereafter, Pioneer shall provide EPA with a report on the number of units of OAM1 corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2010 growing season.
7. Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for OAM1 Corn

1. Pioneer must design and implement a comprehensive, ongoing IRM education program designed to convey to OAM1 corn users the importance of complying with the IRM program. The education program shall involve the use of multiple media, *e.g.* face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each OAM1 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements and specifically the need to plant a lepidopteran refuge. Pioneer shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2. Pioneer must design and immediately implement a “bag tag” that will be attached to all bags of OAM1 seed sold and delivered for the 2011 growing season and annually thereafter. The purpose of this bag tag is to remind growers that OAM1 products require a separate 20% lepidopteran refuge, and a 50% refuge requirement in cotton-growing areas. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. A revised PIP product label must be submitted by January 31, 2011.

3. Pioneer must conduct targeted, on-farm compliance assessments for growers who purchase OAM1 seed to ensure growers are compliant with the requirement of a 20% refuge for lepidopteran pests. For the 2010 growing season, Pioneer must conduct at least 500 on-farm assessments or roughly half the number of assessments that Pioneer will contribute to the 2010

Agricultural Biotechnology Stewardship Technical Committee (ABSTC) compliance assurance program assessment for corn borer and stacked products. Beginning in 2011 and annually thereafter, Pioneer will contract with an independent third party to conduct these compliance assessments and target twice the number of on-farm assessments for OAM1 as Pioneer conducts for corn borer and stacked products on an annual basis. The table below reflects the relative number of on-farm assessments for OAM1 based on Pioneer's contribution to the ABSTC compliance assurance program report and is subject to change with time as appropriate.

- i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

Number of on-farm assessments conducted by Pioneer

Products	Year: 2010	Year: 2011, annually thereafter
Corn Borer and Stacked Products	1000	1000
OAM1	500	2000
Total	1500	3000

Pioneer must provide a report to EPA summarizing the OAM1 compliance assurance program activities and results for the prior year and plans for the OAM1 compliance assurance program for the current year, by January 31, 2011, and annually thereafter. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report must inform EPA of the number of growers deemed ineligible to purchase Bt corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements.

4. Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
5. Beginning January 31, 2011, Pioneer must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, Pioneer must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Pioneer must either submit a separate report or contribute to the report from the industry working group, ABSTC.

6. The registrant shall revise and expand its Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
7. The registrant will enhance the refuge education program throughout the seed delivery channel:
 - i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
 - ii. As stated in 6)c)2), Pioneer must design and immediately implement a “bag tag” that will be attached to all bags of OAM1 seed sold and delivered for the 2011 growing season and annually thereafter. The purpose of this bag tag is to remind growers that OAM1 products require a separate 20% lepidopteran refuge, and a 50% refuge requirement in cotton-growing areas. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. A revised PIP product label must be submitted by January 31, 2011.
8. The registrant will focus the majority of on-farm assessments on regions with the greatest risks for resistance:
 - i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
 - ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.
9. The registrant will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirement:
 - i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.
10. The registrant will contract with third parties to perform on-farm assessments of compliance with refuge requirements:
 - i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment
11. The registrant will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.
12. The registrant will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by the registrant, seed supplier, or third party assessor, after completing the assessment process;
- ii. The registrant will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access to Pioneer Hi-Bred's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

d) Insect Resistance Monitoring and Remedial Action Plan for OAM1 Corn

The Agency is imposing the following conditions for this lepidopteran toxin:

The registrant will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

The registrant shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; S WCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
 - determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
 - estimating the resistance-allele frequency in the original population;
 - determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, the registrant will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

The registrant will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. The registrant will instruct its customers to contact them if such incidents occur. The registrant will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), the registrant will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, the registrant will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, the registrant will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by the registrant:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- The registrant will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. The registrant will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

The Agency is imposing the following conditions for this corn rootworm toxin:

In addition to the existing two-pronged approach to insect resistance monitoring (monitoring insect populations using the diet bioassay and investigations of field reports) that are required for Cry34/35 for Herculex Rootworm Insect Protection (29964-4) and Herculex Xtra Insect Protection (29964-5), Pioneer must also conduct enhanced monitoring using the Sublethal Seedling Assay as a complement to the diet bioassay method. Pioneer must submit a detailed OAM1/OAMRW-specific resistance monitoring plan to the Agency by December 1, 2010.

With respect to the implementation of the Sublethal Seedling Assay:

1. Pioneer must monitor for resistance and or changes in target pest susceptibility that will lead to increased injury potential in western and northern corn rootworm feeding on the rootworm component of OAM1 products. Sampling must be focused in the four regions of highest risk of resistance development: Region – 1 (Illinois, Indiana); Region 2 (Iowa, Missouri), Region 3 (Nebraska and Kansas), and Region 4 (Minnesota, South Dakota and Wisconsin).
2. Pioneer must provide the EPA its detailed western corn rootworm resistance monitoring plan for approval by December 1, 2010, and its northern corn rootworm resistance monitoring plan for approval by December 1, 2011. These plans will include baseline (benchmark) susceptibility data and an enhanced annual resistance monitoring plan. The reports will contain:
 - Sampling scheme: annual collection should target a range of 16-20 western and/or northern rootworm populations (4-5 per region), with a minimum number of 2,000 beetles collected per population.
 - Bioassay methodology (precision, detection level, etc.). Pioneer must bioassay a target of 3000 larvae on 59122 plants for each population.
 - A description of how monitoring results relate to and are predictive of changes in field efficacy, and change in injury potential to DAS-59122-7 constituting product failure and development of a remedial action plan.

3. Pioneer will provide the EPA with an annual OAM1 resistance monitoring report by August 31st of each year beginning with 2011 for western corn rootworm and 2012 for northern corn rootworm, reporting on populations collected the previous year. In addition to screening of wide-area corn rootworm populations as outlined above, for the second prong of resistance monitoring Pioneer must investigate grower, extension specialist or consultant reports of less-than-expected efficacy or field performance of OAM1 products.

e) Remedial Action Plan for Corn Rootworm and OAM1 Corn

The remedial action plan is designed as a tiered approach for mitigating western and northern corn rootworm resistance development specifically due to the commercialization of OAM1 corn. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed.

Pioneer will complete a benchmark study of susceptibility of western corn rootworm using the Sublethal Seedling Assay and analyze field efficacy data to set a benchmark for expected levels of damage to finalize the OAM1 remedial action plan by December 1, 2010, so that decision points regarding crop damage and target pest resistance are established, and a remedial action plan can be initiated when needed. Although northern corn rootworm is difficult to rear in the laboratory, Pioneer will attempt to complete a benchmark study for susceptibility of northern corn rootworm using the Sublethal Seedling Assay.

1. Suspected Resistance from Population Monitoring

Definition of Suspected Resistance - Resistance will be suspected if investigations of target pest injury potential to OAM1 maize from the Sublethal Seedling Assay show that:

- Injury potential of a target pest population obtained as part of the annual insect monitoring program has increased to a level representative of product failure in field conditions;
- The seeds used in the investigation of this population's injury potential contain Cry34/Cry35Ab1 at levels representative of (and in the same genetic background as) the benchmark study; and
- The change in injury potential has been documented as a heritable characteristic of the target pest population and not a result of experimental error.

If resistance is "suspected", Pioneer will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment and/or crop rotation or use of soil or seed-applied insecticides at rates providing corn rootworm control the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

2. Confirmed Resistance from Population Monitoring

Definition of Confirmed Resistance - Resistance will be confirmed if all of the following criteria are met by progeny from a subsequent rootworm population collected from the area of "suspected resistance" the following year:

- Injury potential of the subsequent field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure;
- Subsequent populations collected from the area and assayed show that the results are repeatable; and
- Continued monitoring of the area suggests that the change is spreading.

3. Suspected Resistance – Investigation of Field Reports

The registrant will follow up on grower, extension specialist or consultant reports of unexpected product performance due to corn rootworm species listed on the label. The registrants will instruct its customers to contact them if such incidents occur. The registrants will investigate all such reports submitted to the company or the company's representatives.

- Confirm the corn in question is rootworm-active *Bt* corn;
- Confirm the field in question contains the correct blend rate of refuge corn;
- Confirm that species not susceptible to the protein are not responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that all other reasonable causes based on historical experience for the observed root damage have been ruled out;
- If not due to other reasons, the registrant will conduct a thorough investigation of the factors known to affect the manifestation of corn rootworm feeding damage.
- If the investigation fails to rule out target pest resistance as the cause, resistance is suspected.

If resistance is "suspected", Pioneer will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment, crop rotation the following year or use of soil or seed insecticides the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

Pioneer will collect insects as soon as possible from the area for laboratory studies to test for resistance by comparing with benchmark susceptibility data. These studies will be performed following the same laboratory protocols as used for the benchmark determination and monitoring programs.

4. Confirmed Resistance – Investigation of Field Reports

- Injury potential of the field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- Subsequent populations collected from the area and assayed show that the results are repeatable;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure; and
- Continued monitoring of the area suggests that the change is spreading.

5. Remedial Action

When resistance is "confirmed", the following steps will be taken:

- The EPA will receive notification within 30 days of confirmed resistance;
- Affected customers and Extension specialists will be immediately notified about confirmed resistance;
- Affected customers and Extension specialists will be strongly encouraged to implement alternative CRW control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year;
- Within 60 days of notification, Pioneer and EPA will jointly determine the extent of the mitigation needed and determine whether sales should be stopped on an appropriate geographic (i.e., county or regional) basis; and
- Pioneer will develop a case-specific resistance mitigation action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Pioneer will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by the EPA prior to implementation. The resistance management plan could include such measures layering additional technologies in future OAM1 products.

f) Remedial Action Plan for lepidopteran pests and OAM1 Corn

When field resistance is confirmed (as previously defined), the following steps will be taken by the registrant:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control

measures) , alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- The registrant will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. The registrant will consult with appropriate stakeholders in the development of the action plan. and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e .g. growers, consultants, extension agents, seed distributors, university cooperators and state/ federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

g) Refuge Assurance Program for OAM1 Corn

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure OAM1 products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
 2. ISO 9000 Standard Operating Procedures for the blending process;
 3. Calibration of blending equipment; and
 4. Records and data retention records for seed blend products.
- Calibration records - Pioneer will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
 - Blend proportion records (weight and kernel based) - Pioneer will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an OAM1 product by seed lot.

All records must be maintained at the Pioneer blending facility and must be available for the EPA review upon request.

h) Annual Reporting Requirements for OAM1 Corn

1. Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
2. Grower Agreements: number of units of OAM1 corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2011;
3. Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2011;
4. Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2011;
5. Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2011;
6. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011 for western corn rootworm and 2012 for northern corn rootworm.

Registrant	Registration #	Active Ingredient	Original Registration Date	Status	Expiration Date
Pioneer/Dupont	29964-10	Optimum AcreMax RW (OAM RW) Seed Blend of Herculex RW + Non- <i>Bt</i> corn	30 April 2010	Conditional (amended 29 September 2010)	30 September 2012

- 1] The subject registration will automatically expire on midnight September 30, 2012.
- 2] The subject registration will be limited to a seed mix of DAS-59122-7 (Cry34Ab1/Cry35Ab1) corn seed blended with not less than 10% non-*Bt* corn seed.
- 3] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

Because OAMRW controls corn rootworm pests and contains an integrated corn rootworm refuge, no additional refuge is required. When a grower plants a bag of OAMRW, all refuge requirements are fully and automatically met for this product. Therefore, grower agreements (demonstrating persons purchasing OAMRW corn will annually affirm that they are contractually bound to comply with requirements of the insect resistance management (IRM) program) and other associated stewardship documents are neither necessary nor required.

Targeted on-farm compliance assessments are neither necessary nor required for OAMRW because the refuge is automatically implemented when planting this product.

OAMRW may be used as the Lepidopteran refuge for OAM1. In this case, on-farm assessments to ensure that the Lepidopteran refuge is planted and placed appropriately would be covered by OAM1 grower education, targeted on-farm assessments and stewardship documents.

- 5] Submit the following data in the timeframes listed:

Study Type	Required Data	Due Date
Insect Resistance Management	Pioneer must implement an enhanced resistance monitoring plan for OAMRW. Pioneer must provide the Agency with a baseline (benchmark) study that shows the susceptibility of western corn rootworm populations (WCRW) in the Sublethal Seedling Assay prior to the large-scale introduction of OAMRW. Although northern corn rootworm (NCRW) is difficult to rear, Pioneer must	12/1/2010 for WCRW
		12/1/11 for NCRW

	attempt to obtain benchmark susceptibility data for NCRW as well.	
Insect Resistance Management	Pioneer must submit a detailed OAMRW-specific resistance monitoring and remedial action plan, including an analysis to determine the expected field performance criteria for OAMRW products so that unexpected damage can be benchmarked. Pioneer will update the plan by 12/1/2012, if needed, based on continued field evaluation of OAM1 performance.	12/1/2010

6] Pioneer must do the following Insect Resistance Management Program for OAMRW.

The required IRM program for OAMRW corn must have the following elements:

- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry34Ab1/Cry35Ab1 proteins in the target insects;
- Requirements regarding a “remedial action plan,” that contains measures Pioneer would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request) on or before January 31st of each year, beginning in 2011.

a) Insect Resistance Monitoring for OAMRW Corn

In addition to the existing two-pronged approach to insect resistance monitoring (monitoring insect populations using the diet bioassay and investigations of field reports) that are required for Cry34/35 for Herculex Rootworm (29964-4), Pioneer must also conduct enhanced monitoring using the Sublethal Seedling Assay as a complement to the diet bioassay method. Pioneer must submit a detailed OAM1/OAMRW-specific resistance monitoring plan to the Agency by December 1, 2010.

With respect to the implementation of the Sublethal Seedling Assay:

1. Pioneer must monitor for resistance and or changes in target pest susceptibility that will lead to increased injury potential in western and northern corn rootworm feeding on the rootworm component of OAMRW products. Sampling must be focused in the four regions of highest risk of resistance development: Region – 1 (Illinois, Indiana); Region 2 (Iowa, Missouri), Region 3 (Nebraska and Kansas), and Region 4 (Minnesota, South Dakota and Wisconsin).
2. Pioneer must provide the EPA its detailed western corn rootworm resistance monitoring plan for approval by December 1, 2010, and its northern corn rootworm resistance monitoring plan for approval by December 1, 2011. These

plans will include baseline (benchmark) susceptibility data and an enhanced annual resistance monitoring plan. The reports will contain:

- Sampling scheme: annual collection should target a range of 16-20 western and/or northern rootworm populations (4-5 per region), with a minimum number of 2,000 beetles collected per population.
 - Bioassay methodology (precision, detection level, etc.). Pioneer must bioassay a target of 3000 larvae on 59122 plants for each population.
 - A description of how monitoring results relate to and are predictive of changes in field efficacy, and change in injury potential to DAS-59122-7 constituting product failure and development of a remedial action plan.
3. Pioneer will provide the EPA with an annual OAMRW resistance monitoring report by August 31st of each year beginning with 2011 for western corn rootworm and 2012 for northern corn rootworm, reporting on populations collected the previous year.

In addition to screening of wide-area corn rootworm populations as outlined above, for the second prong of resistance monitoring Pioneer must investigate grower, extension specialist or consultant reports of less-than-expected efficacy or field performance of OAMRW products.

b) Remedial Action Plan for Corn Rootworm and OAMRW Corn

The remedial action plan is designed as a tiered approach for mitigating western and northern corn rootworm resistance development specifically due to the commercialization of OAMRW corn. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed.

Pioneer will complete a benchmark study of susceptibility of western corn rootworm using the Sublethal Seedling Assay and analyze field efficacy data to set a benchmark for expected levels of damage to finalize the OAMRW remedial action plan by December 1, 2010, so that decision points regarding crop damage and target pest resistance are established, and a remedial action plan can be initiated when needed. Although northern corn rootworm is difficult to rear in the laboratory, Pioneer will attempt to complete a benchmark study for susceptibility of northern corn rootworm using the Sublethal Seedling Assay as well.

1. Suspected Resistance from Population Monitoring

Definition of Suspected Resistance - Resistance will be suspected if investigations of target pest injury potential to OAMRW maize from the Sublethal Seedling Assay show that:

- Injury potential of a target pest population obtained as part of the annual insect monitoring program has increased to a level representative of product failure in field conditions;
- The seeds used in the investigation of this population's injury potential contain

Cry34/Cry35Ab1 at levels representative of (and in the same genetic background as) the benchmark study; and

- The change in injury potential has been documented as a heritable characteristic of the target pest population and not a result of experimental error.

If resistance is "suspected", Pioneer will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment and/or crop rotation or use of soil or seed-applied insecticides at rates providing corn rootworm control the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

2. Confirmed Resistance from Population Monitoring

Definition of Confirmed Resistance - Resistance will be confirmed if all of the following criteria are met by progeny from a subsequent rootworm population collected from the area of "suspected resistance" the following year:

- Injury potential of the subsequent field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure;
- Subsequent populations collected from the area and assayed show that the results are repeatable; and
- Continued monitoring of the area suggests that the change is spreading.

3. Suspected Resistance – Investigation of Field Reports

The registrant will follow up on grower, extension specialist or consultant reports of unexpected product performance due to corn rootworm species listed on the label. The registrants will instruct its customers to contact them if such incidents occur. The registrants will investigate all such reports submitted to the company or the company's representatives.

- Confirm the corn in question is rootworm-active *Bt* corn;
- Confirm the field in question contains the correct blend rate of refuge corn;
- Confirm that species not susceptible to the protein are not responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that all other reasonable causes based on historical experience for the observed root damage have been ruled out;
- If not due to other reasons, the registrant will conduct a thorough investigation of the factors known to affect the manifestation of corn rootworm feeding damage.
- If the investigation fails to rule out target pest resistance as the cause, resistance is suspected.

If resistance is "suspected", Pioneer will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment, crop rotation the following year or use of soil or seed insecticides the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

Pioneer will collect insects as soon as possible from the area for laboratory studies to test for resistance by comparing with benchmark susceptibility data. These studies will be performed following the same laboratory protocols as used for the benchmark determination and monitoring programs.

4. Confirmed Resistance – Investigation of Field Reports

- Injury potential of the field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- Subsequent populations collected from the area and assayed show that the results are repeatable;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure; and
- Continued monitoring of the area suggests that the change is spreading.

5. Remedial Action

When resistance is "confirmed", the following steps will be taken:

- The EPA will receive notification within 30 days of confirmed resistance;
- Affected customers and Extension specialists will be immediately notified about confirmed resistance;
- Affected customers and Extension specialists will be strongly encouraged to implement alternative CRW control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year;
- Within 60 days of notification, Pioneer and EPA will jointly determine the extent of the mitigation needed and determine whether sales should be stopped on an appropriate geographic (i.e., county or regional) basis; and
- Pioneer will develop a case-specific resistance mitigation action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Pioneer will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by the EPA prior to implementation. The resistance management plan could include such measures layering additional technologies in future OAMRW products.

c) Refuge Assurance Program for OAMRW Corn

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure OAMRW products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
 2. ISO 9000 Standard Operating Procedures for the blending process;
 3. Calibration of blending equipment; and
 4. Records and data retention records for seed blend products.
- Calibration records - Pioneer will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
 - Blend proportion records (weight and kernel based) - Pioneer will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an OAMRW product by seed lot.

All records must be maintained at the Pioneer blending facility and must be available for the EPA review upon request.

d) Annual Reporting Requirements for OAMRW Corn

1. Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
2. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011 for western corn rootworm and 2012 for northern corn rootworm.